Aspect Medical Systems

A-2000™
BISPECTRAL INDEX™ (BIS™)
MONITORING SYSTEM

OPERATING MANUAL

Rx only

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Considerations for Using BIS Monitoring

Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. ***Reliance on the BIS alone for intraoperative anesthetic management is not recommended.*** As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders, those taking other psychoactive medications and in children below the age of one.

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ABOUT THIS MANUAL

This Operating Manual contains all of the information you need to set up and operate the Aspect Medical Systems' A-2000 BIS Monitoring System (Figure 3). It also includes specific cleaning and test procedures you may occasionally be required to perform. Although this manual is intended for trained medical personnel, it does not assume prior knowledge or experience with operator-programmable medical electronics devices.

Keep this Operating Manual with the A-2000 for use by the operator. This manual is also intended to be a service information manual for service technicians or biomedical engineering personnel.

Section 1 discusses important "Safety Precautions." Before attempting to set up or use the A-2000, please familiarize yourself with the safety information provided in this section.

Section 2 covers A-2000 installation, including system checkout, environmental considerations, equipment and supplies needed, basic connections and setup.

Section 3 explains how to operate the A-2000 under normal conditions. It also covers advanced features such as software updates and data transfer.

Section 4 serves as a quick reference for users who are already familiar with the system.

Section 5 discusses the features and capabilities of the A-2000 system.

Section 6 covers normal care and cleaning procedures and maintenance, which should be performed by the operator on a regular basis.

Section 7 covers diagnostics and troubleshooting and includes a summary of error messages and actions that should be taken by the operator.

Section 8 details the system specifications, product warranty, and the software license agreement.

Section 9 provides additional information on processed variables, and a menu map and listing.

INTRODUCING THE A-2000 BIS MONITORING SYSTEM

INDICATIONS FOR USE

The Aspect A-2000 EEG Monitor with BIS is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.* Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

INTRODUCTION

The A-2000 BIS Monitoring System is a user-configurable patient monitoring system designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The A-2000™ processes raw EEG signals to produce a single number, called the Bispectral Index, or BIS, which correlates with the patient's level of hypnosis.

The A-2000 monitor display consists of:

- The current BIS number
- Trend plots of processed EEG parameters
- Raw EEG waveforms in real time
- Density Spectral Arrays (DSA)
- Numeric BIS log
- Various signal quality indicators (EMG, SQI).
- Suppression Ratio and Burst Count number.

The system performs self-tests to ensure that the monitor and its components are functioning properly and that impedance levels of patient sensors are within acceptable limits. Easy-to-use menus allow the user to mark events, review and clear stored data, and change the data display.

* Gan TJ, Glass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. **Bispectral Index Monitoring Allows Faster Emergence and Improved Recovery from Propofol, Alfentanil and Nitrous Oxide Anesthesia.** *Anesthesiology* October 1997; (4) 87:808-15.

SECTION 1
1 SAFETY PRECAUTIONS

INTRODUCTION

Caution:
Carefully read this entire manual before using the monitor in a clinical setting.

WARNINGS, CAUTIONS, AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A WARNING advises against certain actions or situations that could result in personal injury or death.
- A CAUTION advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.
- A NOTE provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols used on the A-2000 appears at the end of this section.

1.1 WARNINGS

GROUND WIRE LEAKAGE CURRENT MUST BE CHECKED WHENEVER INSTRUMENT CASE IS OPENED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN.

EXPLOSION HAZARD: DO NOT USE THE A-2000 IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS. WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST BEFORE FURTHER USE.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE A-2000 SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

FOR A-2000s USED OUTSIDE OF NORTH AMERICA: A HARMONIZED LINE CORD WITH CONDUCTORS HAVING A CROSS SECTIONAL AREA GREATER THAN 0.75 mm^2 MUST BE USED.

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS, INCLUDING THE NEUTRAL ELECTRODE, SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS IN THE HIGH-FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE A-2000.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA), AS HAZARDOUS GASES MAY RESULT.

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 601-1 AND/OR IEC 601-1-1 HARMONIZED NATIONAL STANDARD.**

REPLACE FUSES ONLY WITH ONE OF THE FOLLOWING PARTS:
Aspect P/N 430-0006, 1.25 Amps, 250V, 5x20mm
Littelfuse 217 Series, 1.25 Amps, 250V, 5x20mm
Wickmann 193 Series, 1.25 Amps, 250V, 5x20mm

ALWAYS REPLACE BOTH FUSES TOGETHER, EVEN IF ONLY ONE HAS FAILED.

1.2 CAUTIONS

Read this entire manual carefully before using the monitor in a clinical setting.

Do not autoclave the Digital Signal Converter or Monitor. Autoclaving will seriously damage both components.

Do not block fan output. Keep at least three 3 inches of unobstructed space between rear of instrument and wall and other instruments. Do not allow other instruments to block airflow. Do not block ventilation inlet holes on the underside of monitor.

Do not open Digital Signal Converter for any reason. The seal to prevent liquids from entering the Digital Signal Converter may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

Mixing of system configurations will increase sensor and hardware inventory requirements and may create user and support issues.

Each BIS sensor type has its own placement method. Be sure to carefully follow the appropriate package directions.

The A-2000 has been designed to operate with a disposable BIS Sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Check the battery periodically, by operating an A-2000 that has been disconnected from the wall socket and that has been charging the battery for at least 4 hours. After long periods of storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity.

If the A-2000 fails to operate reliably from the battery for 20 minutes, battery replacement is required.

The A-2000 contains an internal Nickel-Metal-Hydride battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for servicing of battery.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connector can interfere with PIC performance.

The A-2000 system complies with the electromagnetic compatibility requirements of EN60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Consult Aspect Medical Systems Technical Support for assistance.

When connecting or disconnecting Digital Signal Converter, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

A-2000 is a trademark of Aspect Medical Systems, Inc.

Bispectral Index, BIS, the BIS logo, and Zipprep are trademarks of Aspect Medical Systems, Inc. and are registered in the U.S.A., E.U. and other countries.

1.3 KEY TO SYMBOLS

ON (power; connection to the mains)

OFF (power; disconnection from the mains)

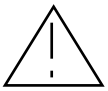
Audible Alarm Silenced

Operating on Battery

Type BF Equipment

Type BF Equipment Defibrillator-proof

Attention, Consult Accompanying Documents

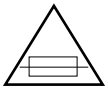
J1 

Attention, J1 RS-232 Serial Port, Consult Accompanying Documents

J2

Attention, J2 Printer Port, Consult Accompanying Documents

Figure 1 - Symbol Key

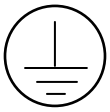


Fuse, Replace only with same Type and Rating

Equipotential

Alternating Current

Dangerous Voltage



Protective Earth (ground)

Storage Temperature Limits

Figure 1 Symbol Key (concluded).

SECTION 2
2 INSTALLATION AND PREPARATION FOR USE

INTRODUCTION
This section provides installation instructions for the Aspect A-2000 BIS Monitor, Digital Signal Converter, and accessories. It includes:

- Installation checklist
- Proper environment
- Required equipment and supplies
- Cable connections
- Start and shutdown procedures
- Menu settings

2.1 A-2000 BIS MONITOR INSTALLATION AND CHECKOUT

1. Open packages and inspect for all components:
   - Monitor with power cable
   - DSC
   - PIC (Patient interface cable, connects DSC to patient)

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.

3. Power up monitor by pressing power switch (lower, right side of case).
   - Verify beep tone as power switch is activated.
   - Verify fan (rear case wall) moves air outward.
   - Verify all power on self-tests complete successfully (approx. 30 seconds).
   - Verify next screen says ‘CONNECT DSC CABLE TO FRONT OF MONITOR.’

4. Connect DSC with PIC and Sensor.
   - Verify DSC test completes.
   - Verify SENSOR CHECK screen displays.

5. Exit from SENSOR CHECK screen by passing impedance check or by exiting with MENU/EXIT key.

6. Disconnect power cord from rear of monitor.
   - Verify ‘OPERATING ON BATTERY BACKUP (E33)’ is displayed.
   - Verify battery icon displays in BIS banner.

7. Reconnect power cord.
   - Verify battery icon is not displayed in BIS banner.
   - Verify ‘OPERATING ON BATTERY BACKUP (E33) is not displayed.

8. Do keyboard checkout:
   - Press SILENCE key — Verify icon shows at BIS banner.
   - Press ARROW BACK key — Verify REVIEW MODE screen displays.
   - Press MENU/EXIT key — Verify REVIEW MODE screen exits.

- Press ARROW AHEAD key Verify REVIEW MODE screen displays.
- Press MENU/EXIT key Verify REVIEW MODE screen exits.
- Press MENU/EXIT key Verify Setup menu displays.
- Press UP ARROW key Verify highlight bar moves up with each press.
- Press DOWN ARROW key Verify highlight bar moves down with each press.
- Press SELECT key Verify that highlighted menu line is selected.
- Press MENU/EXIT until BIS banner is displayed.

9. End of install.

2.2 ENVIRONMENT

2.2.1 Shipping and Storage Environment

The monitor and its accessories can be stored or shipped within the following environmental limits. Note that these limits apply to non-operational storage and shipping situations.

Temperature	-20°C to +60°C
Humidity	15% to 95% (non-condensing)
Pressure	360 mmHg to 800 mmHg

Protect the monitor from sudden temperature changes that can lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

2.2.2 Operating Environment

The A-2000 is not designed for use in areas containing flammable gases or vapors.

WARNING!

EXPLOSION HAZARD: DO NOT USE THE A-2000 IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

Temperature: The Aspect A-2000 Monitor is designed to operate safely at a room temperature of 5°C to 40°C. Conditions that exceed these limits could affect reliability.

Humidity: The monitor is designed to operate within specifications at a relative non-condensing humidity of 15% to 95%.

Pressure: The monitor will operate satisfactorily at or above sea level, and is unaffected by extremes or changes in altitude within atmospheric pressures of 360 mmHg to 800 mmHg.

2.2.3 Power Requirements and System Grounding

The A-2000 BIS Monitor requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 1 ampere maximum (including printer load).

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

WARNING!

FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE A-2000 SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

FOR A-2000s USED OUTSIDE OF NORTH AMERICA - A HARMONIZED LINE CORD WITH CONDUCTORS HAVING A CROSS SECTIONAL AREA GREATER THAN 0.75 mm^2 MUST BE USED.

2.2.4 Site Preparation: Mounting the Monitor

Aspect Medical Systems, Inc. strongly recommends permanent mounting of the A-2000 monitor to the anesthesia machine to enhance safety and facilitate ease-of-use. Please contact your local representative or Aspect to discuss mounting options.

WARNING!

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

2.2.4.1 Direct Shelf Mounting

The A-2000 has a centrally located screw hole on its underside, in which a #10-24 machine screw can be used to secure the monitor to a shelf (via through-hole). Engagement length of this screw hole is .23 inches (.58 cm). If a printer is attached, use the holes on the underside of the printer.

2.2.4.2 Mounting the Monitor using the Pole Clamp

To mount the monitor to a secure vertical pole (1/2" - 1½" in diameter):

1. Place pole within clamp bracket and tighten screw using the black finger knob. Make sure that there is enough space above the clamp so that you have a few inches to slide the monitor in from above.
2. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp, and the monitor should snap securely into place.

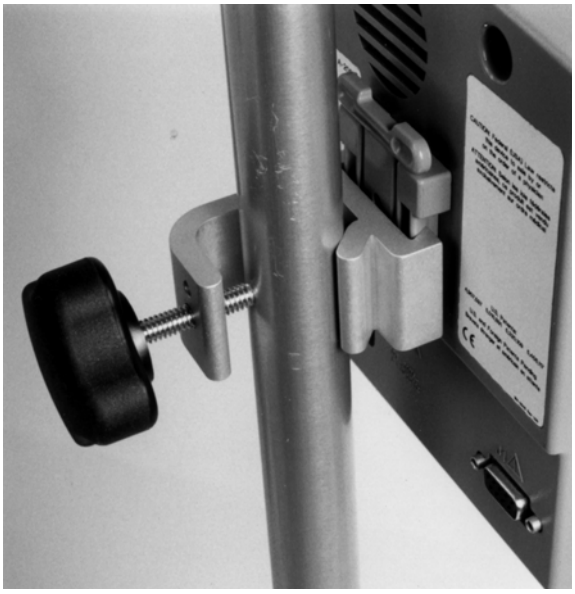


Figure 2 Pole Clamp

To remove the monitor, press tab on top of clamp shoe before sliding monitor up.

The pole clamp may be locked onto the monitor so that the two do not get separated. To do this:

1. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp and the monitor should snap securely into place.
2. Make sure that set screw hole on pole clamp aligns with corresponding hole on clamp shoe.
3. Remove black knob screw from pole clamp.
4. Using the Allen wrench supplied, secure pole clamp to monitor with the set screw provided.
5. Replace black knob screw.
6. To attach to pole, place pole within clamp bracket and tighten screw using the black finger knob.

2.2.4.3 Optional Mounting Accessories

For information on optional mounting accessories, request Aspect's "Monitor Mounting Solutions" booklet (part number 070-0031)

2.3 THE A-2000 BIS MONITORING SYSTEM - EQUIPMENT AND SUPPLIES

The A-2000 BIS Monitoring System consists of the following basic components:

- A-2000 BIS Monitor
- Digital Signal Converter (DSC)
- Patient Interface Cable (PIC)
- BIS Sensor
- Detachable Power Cord

A pole clamp is also included; however its use is optional. The exact model of DSC, PIC and compatible sensors depends on the system configuration. Please consult section 2.2.4 for more detail. Contact Aspect or your local representative for information on additional equipment and accessories.

Figure 3 The A-2000 BIS Monitoring System

2.3.1 The BIS Monitor

2.3.1.1 Front Panel

The front panel of the BIS Monitor contains the Digital Signal Converter (DSC) port and the controls needed for normal operation. See Figure 4.

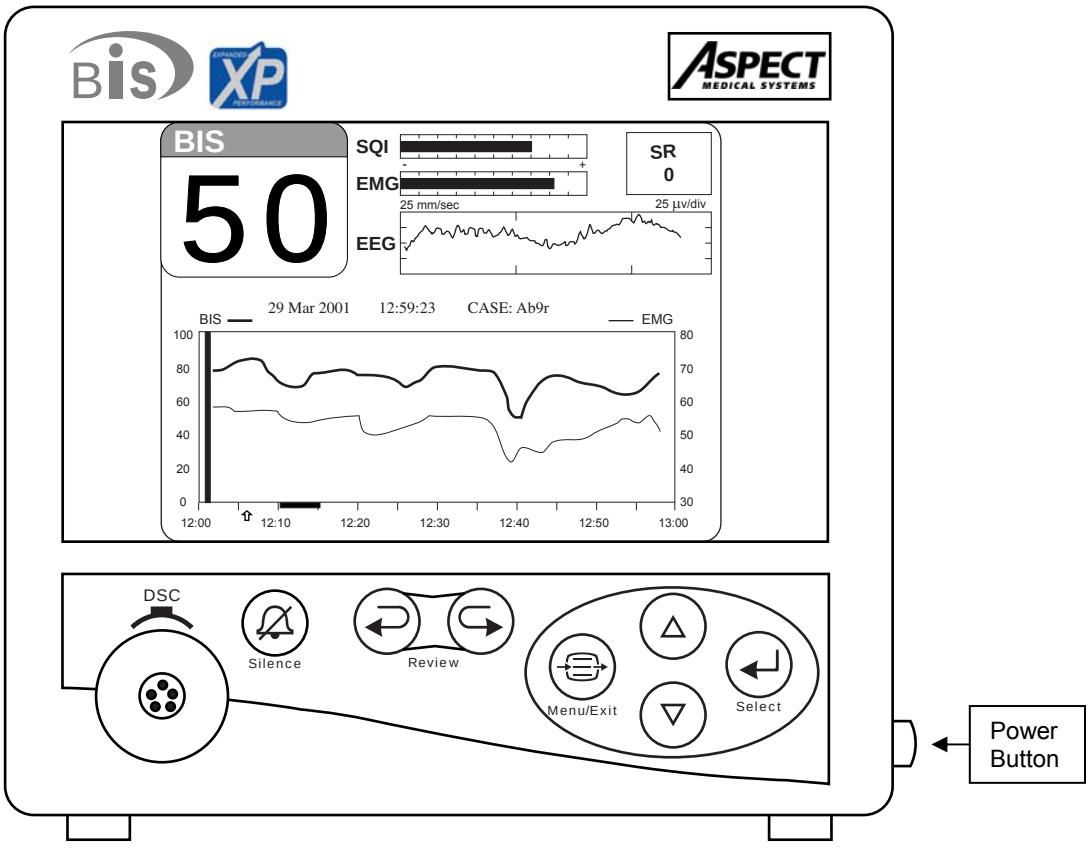


Figure 4 Front Panel (Example Illustration)

Front Panel Controls:

	The [SILENCE] key toggles audible alarms on and off.
	The left [←] and right [→] arrow keys are used to enter Review mode and to scroll data backward and forward in time. In the BIS Log, they show the previous [←] or next [→] screen of data.
	The [MENU/EXIT] key is used to enter and exit the Setup Menu. In Review mode it will return the user to the main screen. It is also used to halt certain procedures, such as the sensor check, and to answer "no" to a question.
	The up [↑] and down [↓] arrows are used to move from one menu selection to another. They are also used to increment and decrement values. In the BIS Log, they are used to zoom time out or in (increase or decrease reporting intervals).
	The [SELECT] key is used to move between options within a menu selection, to confirm an entry, and to answer "yes" to a question.

Figure 5 Front Panel Controls

2.3.1.2 Power Button (Side Panel)

The power button is located on the lower right side of the monitor. It powers both the monitor and the digital signal converter when the DSC is connected to the monitor. If a power loss occurs, an internal back-up battery will supply power to the system. **The back-up battery charges when the monitor is plugged into the AC supply and the power is ON.**

2.3.1.3 Rear Panel

The rear panel components are pictured in Figure 6. They include: the fan, clamp shoe, potential equalization terminal, power cord receptacle with fuse holder, and the RS-232 serial port. A printer connection port is located on the bottom underside of the monitor. Only an Aspect-supplied printer will function with this port.

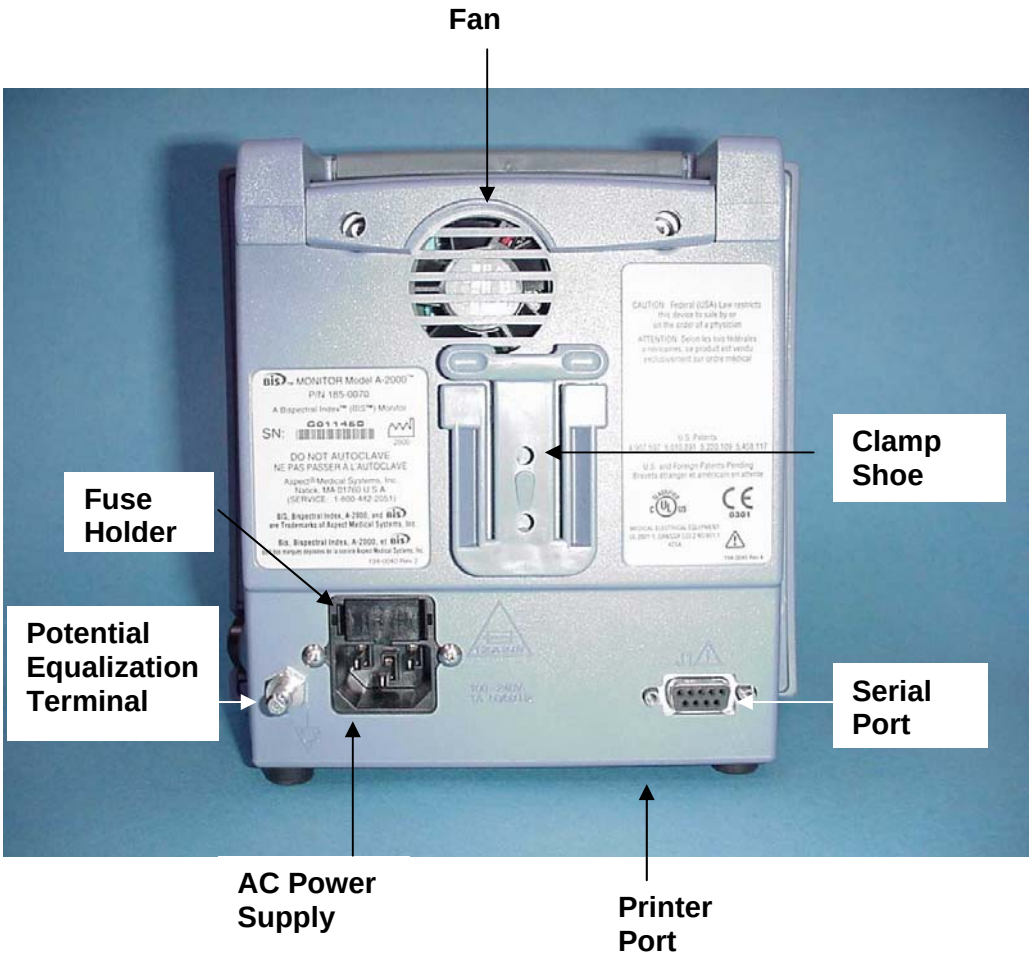


Figure 6 Rear Panel

WARNING!
REPLACE FUSES ONLY WITH ONE OF THE FOLLOWING PARTS:
Aspect P/N 430-0006, 1.25 Amps, 250V, 5x20mm
Littelfuse 217 Series, 1.25 Amps, 250V, 5x20mm
Wickmann 193 Series, 1.25 Amps, 250V, 5x20mm

ALWAYS REPLACE BOTH FUSES TOGETHER, EVEN IF ONLY ONE HAS FAILED.

The **fan** prevents temperature inside the monitor chassis from rising above optimum operating levels.

Caution:

Do not block fan output. Keep at least 3 full inches of unobstructed space between rear of instrument and wall and other instruments. Do not allow other instruments to block airflow. Do not block ventilation inlet holes on the underside of monitor.

The **clamp shoe** allows the monitor to slide into the **pole clamp** so that it can be attached to a ½" – 1 ½" diameter vertical pole.

The **potential equalization terminal** may be used to ground the monitor and its components.

The **power cord receptacle** is used to plug in a three-prong hospital grade power cord to provide power to the monitor and to the DSC when attached.

The **printer port** is provided to attach the monitor to the Aspect A-2000 Printer.

Caution:

The A-2000 system complies with the electromagnetic compatibility requirements of EN60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Consult Aspect Medical Systems Technical Support for assistance.

The **RS-232 serial port** is used to transfer data to and from the monitor. It is also used in testing and in software updates.

WARNING!

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 601-1 AND/OR IEC 601-1-1 HARMONIZED NATIONAL STANDARD.**

2.3.1.4 Integral Battery

A rechargeable nickel-hydride battery inside the monitor provides approximately 20 minutes of back-up power when power cannot be supplied via the power cord. Recharge time is approximately 4 hours.

When the battery reaches a low power condition, the monitor will beep and blink the battery symbol displayed on the screen. In addition, a battery low message will blink continuously on the screen.

Caution:

Check the battery periodically, by operating an A-2000 that has been disconnected from the wall socket and that has been charging the battery for at least 4 hours. After long periods of storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the A-2000 fails to operate reliably from the battery for 20 minutes, battery replacement is required.

The A-2000 contains an internal Nickel-Metal-Hydride battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for servicing of battery.

2.3.2 Digital Signal Converter (DSC)

The Digital Signal Converter is used to receive patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment. The DSC amplifies and digitizes the signals so that they are received clearly by the monitor.

The Digital Signal Converter is shown in Figure 3. The long flexible Monitor Interface Cable connects to the front of the monitor, and the shorter "DSC pigtail" cable connects to the Patient Interface Cable (PIC).

The **attachment clip** on the DSC is used to secure it in a convenient location near the patient's head.

Caution:

Do not open Digital Signal Converter for any reason. The seal to prevent liquids from entering the Digital Signal Converter may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

2.3.3 Patient Interface Cable (PIC)

Aspect's BIS Sensor Patient Interface Cable (see Figure 3) connects the DSC to the BIS Sensor.

2.3.4 BIS Sensor

After the BIS Sensor has been placed correctly on the patient's head, it is connected to the PIC.

2.3.5 A-2000 System Configurations

The chart below details the three A-2000 BIS monitoring system configurations: the BIS XP Platform, the XP Compatible System, and the Standard System.

Component	*A-2000 BIS XP Platform*	*A-2000 XP Compatible*	*A-2000 Standard System*
Monitor	**A-2000 Monitor**	**A-2000 Monitor**	**A-2000 Monitor**
DSC	**DSC-XP***	**DSC-2**	**DSC-2**
PIC	**PIC Plus**	**PIC Plus Adapter**	**PIC-S**
Compatible Sensors**	**BIS Quatro** **BIS Extend** **BIS Pediatric**	**BIS Quatro** **BIS Extend** **BIS Pediatric**	**BIS Standard**

* Some early versions of the A-2000 BIS XP Platform may be supplied with a DSC-3
** BIS Sensor Plus (where sold) is also compatible with the BIS XP Platform and XP Compatible Systems

2.3.5.1 The BIS XP Platform

The BIS XP Platform represents Aspect's top-of-the-line BIS monitoring solution. Operational differences between it and the Standard System include:

- Compatible with new line of sensors including BIS Quatro, BIS Extend, and BIS Pediatric
- DSC-XP with new processing capabilities
- Improved sensor connector with increased comfort in prone patients
- Enhanced sensor troubleshooting via Sensor Data Display (see Section 7.1.3)

2.3.5.2 XP Compatible

The Adapted System offers some of the features of the XP Platform, but at a lower upgrade cost. Operational differences between it and the Standard System include:

- Compatible with BIS Quatro, BIS Extend and BIS Pediatric sensors
- Improved sensor connector with increased comfort in prone patients

2.3.6 Platform Compatibility Considerations

Aspect's **new sensors** (BIS Quatro, BIS Extend and BIS Pediatric) **are only compatible with new BIS systems** (BIS XP Platform and XP Compatible) by virtue of an improved sensor connector (see figure below) and other features.

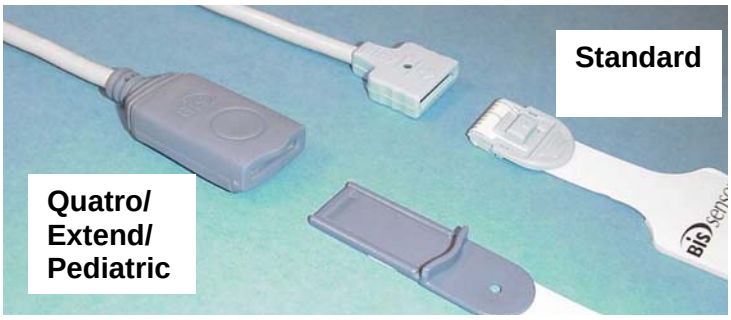


Figure 7 BIS Sensor Connections

Caution:

Mixing of system configurations will increase sensor and hardware inventory requirements and may create user and support issues.

2.3.7 Upgrading A-2000 Standard Systems

Aspect offers two upgrade options for A-2000 systems:

Upgrade Option	Part Number	Components	Resulting System
XP Upgrade Kit	186-0125 (English)	DSC-XP PIC Plus Operating Manual	A-2000 BIS XP Platform
PIC Plus Adapter	186-0126	PIC Plus Adapter (Operating Manual available separately)	A-2000 XP Compatible

Also available is the **Pediatric Upgrade Kit** (P/N 186-0136), which includes a PIC Plus Adapter and 25 BIS Pediatric sensors.

Aspect or your local distributor will help coordinate upgrades including the following:

- Software upgrade (if necessary) to System Software 3.10 or above
- Replacement and return of appropriate cabling (e.g., DSC-2s, PIC-Ss)
- Replacement and return of obsolete BIS sensors (if covered)
- Follow-up in-servicing (e.g., new BIS Quatro or BIS Extend placement)

Contact Aspect or your local distributor at your earliest convenience to schedule your upgrade.

Note:

Customers are encouraged to manage sensor inventory to minimize levels on upgrade day, as Aspect (or distributor) may not cover complete replacement.

2.4 CABLE CONNECTIONS

After you have familiarized yourself with the safety information in the introductory section of this manual and have prepared a suitable environment, follow these steps to prepare the A-2000 system for operation.

1. **Connect the DSC to the monitor**
   Holding the connector with the flat side up, plug the DSC cable into the DSC port on the front of the monitor.

   Once connected, the DSC need not be disconnected again. However, if you wish to disconnect the DSC cable from the monitor, carefully pull on the blue rubber overlay. DO NOT pull on the gray cable.

2. **Connect the PIC to the DSC**
   Attach the Patient Interface Cable to the "DSC pigtail" extending from the DSC unit.

   Note:
   Before connecting, carefully line up the markings on the connectors for proper pin alignment. To disconnect the PIC, grasp the connector housing and pull firmly. DO NOT pull apart by the cable wire.

2.5 START PROCEDURE

To start the instrument:

1. Attach one end of the power cord to the rear panel of the monitor.
2. Plug the other end of the power cord into a properly grounded hospital-grade AC power outlet.
3. Press side panel POWER button. The internal back-up battery charges only when the monitor is powered on and plugged into the AC outlet.

Powering on the monitor will initiate a self test procedure to be certain that the equipment and connections are operating properly. If there is a problem, the system will halt and an error message will appear. Error messages are explained in the Troubleshooting section of this manual.

To **shut the system down**, simply press the POWER button.

2.6 MENU SETTINGS

Before using the A-2000 for the first time, you may need to select the proper language and set the current date and time. Other setting options are discussed in detail in Section 3.

To move from one selection to another, use the up [↑] and down [↓] arrows to highlight the option you desire. Then follow the instructions below:

2.6.1 Language Selection Menu

The A-2000 is designed to support multiple languages. If the screen does not display the desired language, follow these steps to display the Language Selection Menu:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Language Selection Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**. The Language Selection Menu displays.

To change languages:

1. Press **[SELECT]** until the desired language is selected.
2. Use the up [↑] or down [↓] arrows to highlight **Return to Advanced Setup Menu** and press **[SELECT]**. This will redisplay the **Advanced Setup Menu** in the selected language.
3. To make sure that the selected language displays every time the monitor is turned on, use the arrows to highlight **Save Settings**, then press **[SELECT]** to save setting changes.

2.6.2 Time/Date

To set the current time and date:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Time/Date** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]** until the date or time value you wish to update appears in reverse video.
6. Use the up [↑] or down [↓] arrows to increase or decrease the values displayed.
7. Press **[SELECT]** to move to the next date or time value.
8. To save the date or time changes, press **[SELECT]** at the last Time/Date option (minutes). Pressing [Menu/Exit] before this last option aborts previous changes.
9. Press **[MENU/EXIT]** to exit from the Advanced Setup Menu.

Note:

The time/date is initially set for the Eastern Standard Time zone (USA). It will be necessary for you to change the time twice per year using the Time/Date feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

When a time/date is entered that is earlier than the current time/date in the monitor, all data memory will be erased. The prompt, "Clear Data Memory?" will appear to alert you of this. Press [SELECT] to confirm, or press [MENU/EXIT] to abort.

2.6.3 Save Settings

The A-2000 monitor will always power up configured to settings that have been saved in memory. To save the current configuration settings:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.

3. Press **[SELECT]**.
4. Highlight **Save Settings** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]** to save setting changes. The current settings will be saved and the system will exit to the Main Screen.

Note:

The Save Settings option is disabled when in Battery Backup-Low Power condition.

SECTION 3
3 OPERATING THE A-2000

INTRODUCTION

This section covers:

- Preparing for operation
- The sensor check and sensor integrity check
- The monitor screen display
- Software menus and menu selections
- Alternative displays
- Reviewing stored data
- Ending a case
- Data transfer and software update procedures.

Read this section before operating the monitor in a clinical setting.

3.1 PREPARING FOR OPERATION

After you have familiarized yourself with the safety information in the introductory section of this manual, prepared a suitable environment, properly connected the DSC and PIC cables, and completed the settings in the Setup and Advanced Setup Menus, follow these steps to prepare the A-2000 system for operation.

1. Power ON and System Check

Press the button on the lower right side of the monitor to turn the power on. The system will initiate a self-test to make sure that all equipment is operating properly.

2. Attach BIS Sensor to Patient

Prepare sensor site and place the BIS Sensor on the patient in accordance with the instructions included on the sensor packaging.

Cautions:

Each BIS sensor type has its own placement method. Be sure to carefully follow the appropriate package directions.

The A-2000 has been designed to operate with a disposable BIS Sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.

WARNINGS!

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS, INCLUDING THE NEUTRAL ELECTRODE, SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS IN THE HIGH-FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE A-2000.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

3. Secure the DSC

Using the attachment clip, secure the DSC to a convenient location near the patient's head.

4. Attach the BIS Sensor to the PIC

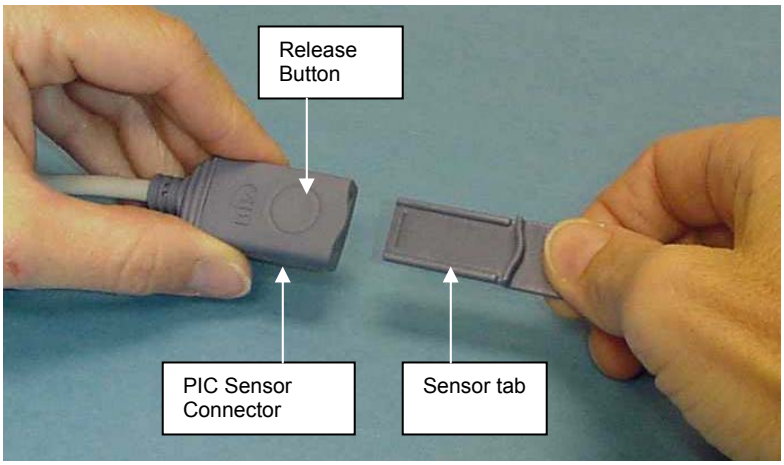


Figure 8 Connecting the PIC (BIS XP Platform and XP Compatible)

BIS XP Platform or XP Compatible: To insert the sensor into the PIC, line up as shown and insert the sensor tab into the PIC sensor connector until an audible "click" is heard. The blank side of the sensor tab (i.e. the side without the computer chip) should be facing up.

Standard System: Line up the arrows and press firmly to ensure a good connection.

For best results, use tape to secure the sensor in place. Adhesive should be used only on the sensor, NOT on the PIC sensor connector.

3.2 THE SENSOR CHECK AND SENSOR INTEGRITY CHECK

A Sensor Check is initiated automatically when the sensor and PIC are connected to the DSC. It may also be initiated by the user in the Setup Menu.

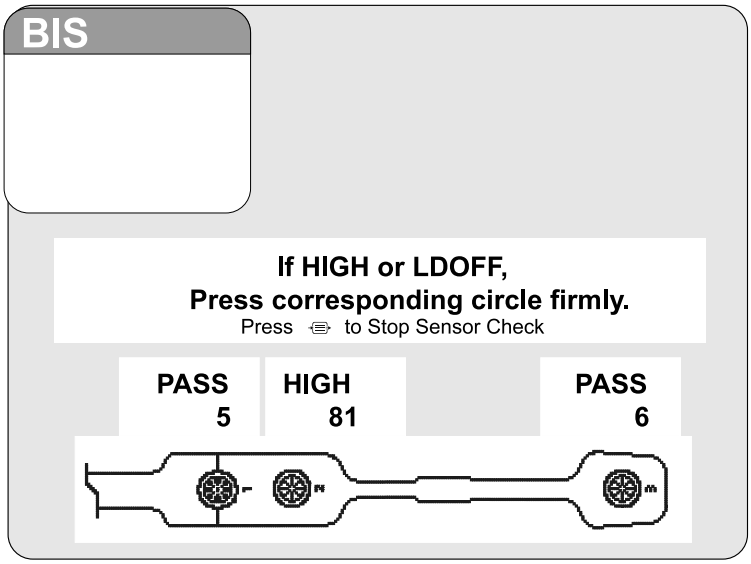


Figure 9 The Sensor Check (BIS Standard and BIS Pediatric sensors)

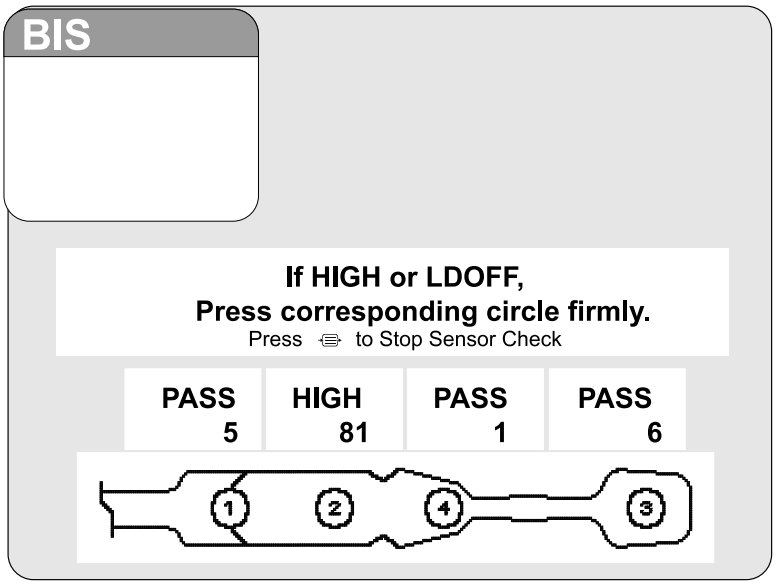


Figure 10 The Sensor Check (BIS Quatro and BIS Extend)

The impedance value for each electrode, in kilo ohms, appears on the screen along with its status:

PASS - An electrode passes if the impedance for that electrode is less than 7.5 kilo ohms. The ground electrode (element #2) must be less than 30 kilo ohms to pass.

HIGH - An electrode is labeled "HIGH" if its impedance value is above 7.5 kilo ohms. As long as the combined impedance (elements #1 and #3) is less than 15 kilo ohms, the sensor check will be considered successful. (BIS Quatro and BIS Extend also check combined impedance of elements #1 and #4). If the combined impedance is over the 15 kilo ohms limit, you will need to re-prep the electrodes and check all connections. The monitor will continue to check impedance until it is acceptable.

NOISE - If the signal from the electrode goes beyond the measurable range, the label "NOISE" will appear.

LDOFF - If a lead is too loose or disconnected, the label "LDOFF" will appear.

The monitor continues updating the values until all impedance values are acceptable. To end the impedance test, press [MENU/EXIT]. The Sensor Check impedance test must be successfully completed before normal processing resumes.

Note:

All signal status messages will be suppressed for 60 seconds after a sensor check has exited. This provides the time for signal quality to recover.

The Sensor Integrity Check (BIS XP Platform only) is also initiated each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

3.3 THE BIS TREND SCREEN DISPLAY

Once the sensor check has successfully completed, monitoring begins and the appropriate information appears on the screen. The BIS trend screen consists of four separate regions (see Figure 11):

- The BIS Numeric Region
- The Message Region
- The Signal Quality Region
- The Graphic Display Region

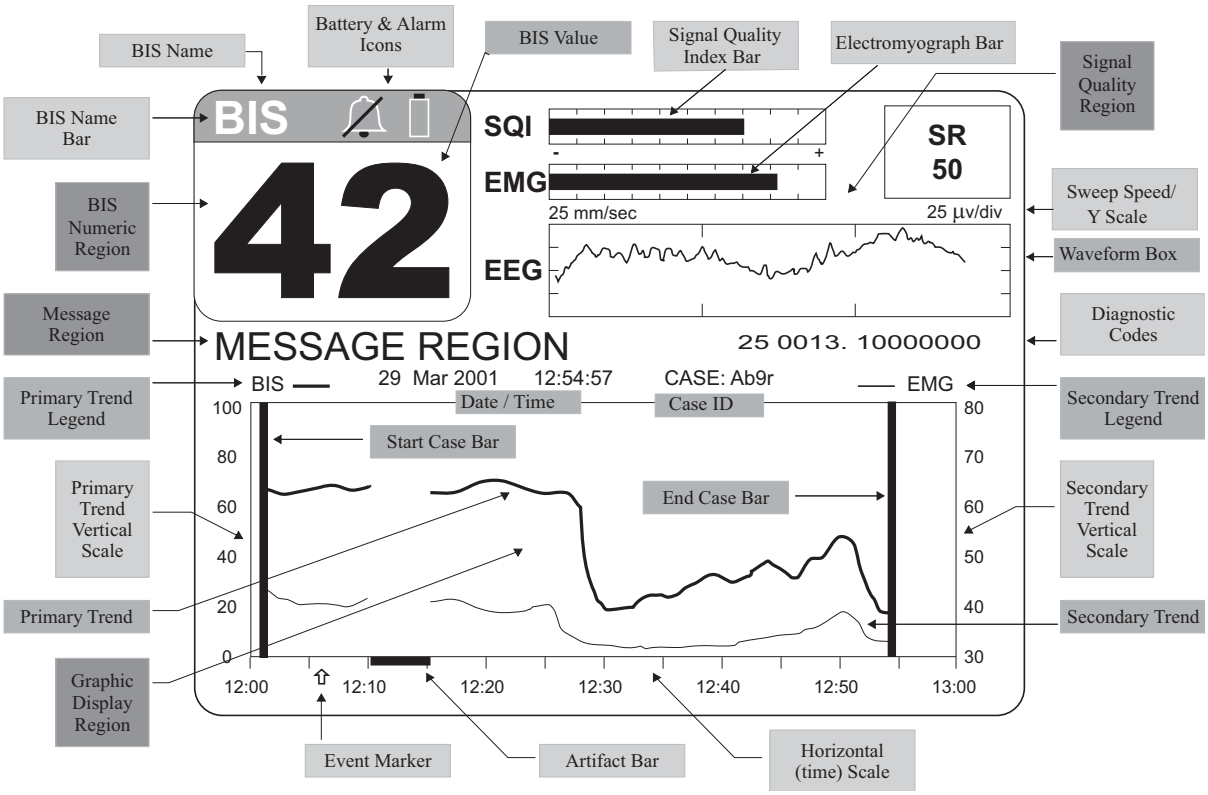


Figure 11 - Screen Regions and Features

3.3.1 The BIS (Bispectral Index) Numeric Region

The BIS Numeric Region is in the upper left corner of the screen and displays the current numeric value of the BIS in a large, easily readable font. The number displayed changes to outlined characters during periods of poor signal quality when SQI is below 50, and disappears altogether when signal quality is very low. If limit alarms have been set, this number will alternately display as a solid or outlined numeric character whenever a limit is reached. This region also displays the alarm silence icon (a slashed bell) when the alarm silence button is activated, the battery icon (which blinks when battery power is low) when the monitor is operating on battery power, and the message, “EXTEND MODE ON” when a BIS Extend sensor is in use. The BIS number is displayed and continuously updated during all display modes.

3.3.2 The Signal Quality Region

The Signal Quality Region is located in the upper right section of the screen. When the [MENU/EXIT] key has been pressed, this area is used to display the Setup Menu. In the BIS Log display, it displays instructions. In all other modes, the following signal quality information is displayed. (Refer to Figure 11.)

3.3.2.1 The Signal Quality Index (SQI) Bar Graph

The SQI is an indication of the quality of the EEG signal that is received and processed into screen data. The SQI graph represents a scale of 0 - 100, marked off at intervals of 10. Optimal signal quality for the EEG channel source is indicated when the bar extends to the right side (+) of the graph.

3.3.2.2 The Electromyograph (EMG) Bar Graph

The EMG graph shows the power (in decibels) in the frequency range 70 - 110 Hz. This frequency range contains power from muscle activity (i.e., electromyography or “EMG”) as well as power from other high-frequency artifacts. A low level of EMG is indicated when the bar is not present or at the left side of the graph.

3.3.2.3 The Electroencephalogram (EEG) Waveform Display

Filtered EEG waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division (default). EEG filters can be turned off and the sweep speed and amplitude can be changed in the Display Parameter Setup screen.

3.3.2.4 The Suppression Ratio (SR) Number

Suppression ratio is a calculated parameter to give the user an indication when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state. For example: SR=11 (isoelectric over 11% of the last 63 second review). The SR is displayed in the upper right corner of the screen.

3.3.2.5 The Burst Count (BURSTS/MIN)

When a BIS Extend sensor is in use, the Burst Count is displayed just below the SR number. Burst Count is an alternative method of quantifying suppression, reported as the number of EEG bursts per minute. When the signal quality is low (SQI less than 15) or when the suppression ratio is less than 5, the burst count is not displayed.

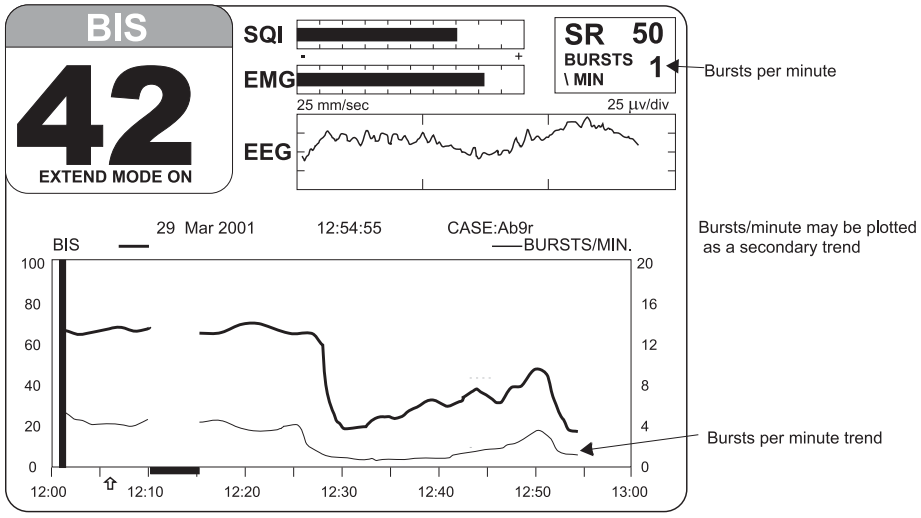


Figure 12 The BIS Trend Display with BIS Extend Sensor in Use

3.3.3 The Message Region

The Message Region is a space reserved for text that appears below the BIS and Signal Quality Regions and extends the full width of the screen. Status and error messages are displayed here. Specific error messages are explained in the Troubleshooting section of this manual.

3.3.4 Graphic Display Region

The Graphic Display Region displays trend graphs of the BIS and an optional secondary variable. During the sensor check procedure, this region of the screen is used to issue instructions and report current status.

The BIS Trend display shows a plot of the Bispectral Index over a 1-hour time period. The BIS trend is indicated with a thick line and its unit markings appear on the left axis. The name BIS is displayed above the left corner of the graph (Figures 12,13).

A secondary variable may be added to the display by selecting "SR", "EMG," or "SQI" in the Advanced Setup Menu. When a BIS Extend sensor is in use, you may select Burst Count (“Bursts/Min”). See Section 3.4.2 for instructions on selecting a secondary variable. The secondary trend is shown with a thin line and its unit markings appear on the right axis. The secondary trend name is displayed above the right corner of the graph.

A thick vertical bar marks the **start of a case** at the time a new case is detected. A similar bar appears at the **end of a case** when in Review Mode or on the printer output. The monitor assumes that a case has ended if the DSC, the PIC or the sensor have been disconnected for more than 15 minutes, or if the monitor has been turned off, then on.

During periods of poor signal quality when SQI is below 50, an **artifact bar** appears along the horizontal axis at the bottom of the graph area. It appears as a hatched line. When signal quality is considered too low to calculate a BIS value, this bar will show prominently as solid white and any trend variables that are adversely affected by artifact will not be displayed.

Event markers may be added to the display by pressing [MENU/EXIT], then selecting [EVENT] from the Setup Menu. Event markers are shown as arrows at the bottom of the Trend Display.

If **alarm limits** for BIS have been set in the Alarm Menu, they will appear as horizontal dotted lines across the graph. When these limits are reached, the BIS number in the upper left corner of the screen will alternately display as a solid or outlined numeric character and the limit line will blink, a message will appear in the Message Region of the screen, and a warning tone will sound (unless the [SILENCE] key has been pressed).

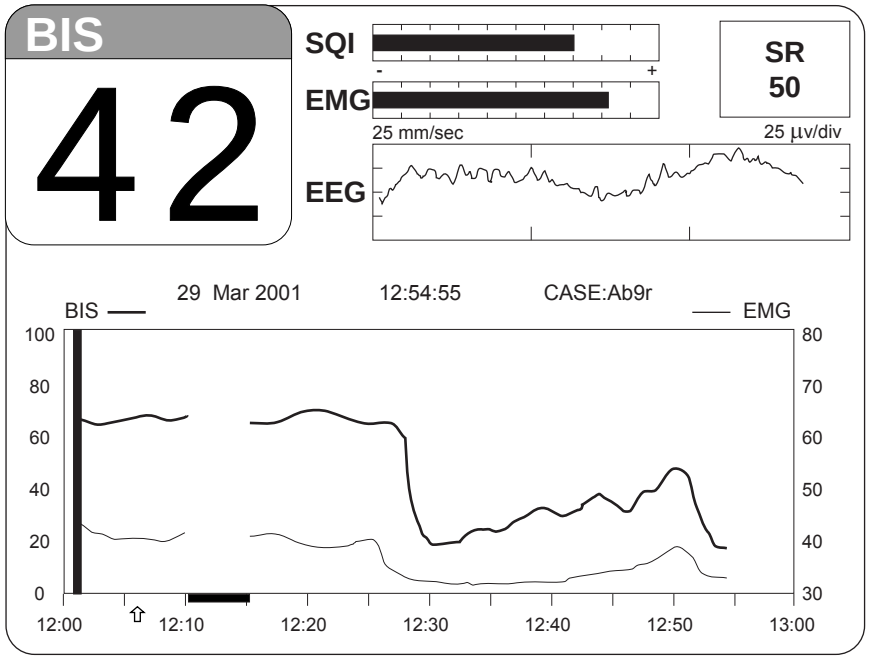


Figure 13 The BIS Trend Display

3.4 THE A-2000 SOFTWARE MENUS AND MENU SELECTIONS

This section discusses the A-2000 software menus and menu selections, including:

- Setup Menu
- Advanced Setup Menu
- Display Parameter Setup screen
- Diagnostic Menu
- Alarm Menu
- Sensor Data Display screen
- System Configuration Menu

Details of the Diagnostic and System Configuration Menus and the Sensor Data Display screen are covered in more detail in Section 7.

3.4.1 Menu Navigation:

	The [MENU/EXIT] key is generally used to enter the Setup Menu and to exit from all other menus. It is also used to halt certain procedures, such as the sensor check, and to answer "no" to a question.
	The left [←] and right [→] arrow keys are generally used to enter Review mode and to scroll data backward and forward in time. In the BIS Log, they show the previous [←] or next [→] screen of data.
	The up [↑] and down [↓] arrows are generally used to move from one menu selection to another.
	The [SELECT] key is used to move between options within a menu selection, to confirm an entry, and to answer "yes" to a question.

Figure 14 Menu Navigation

When a menu is displayed, the default or set values for each line are underlined. The line that is currently selected is highlighted, and the default or set value for that line appears in reverse video. To move to another line, use the up [↑] or down [↓] arrows. To select a particular menu item, or to change a selection, use the [SELECT] key.

3.4.2 The Setup Menu

The Setup Menu can generally be accessed by pressing the [MENU/EXIT] key. Before using the monitor for the first time, you may want to update the Setup Menu with your desired screen settings and the current date and time. You should also familiarize yourself with the various menu options available. These menu options are discussed below. For more detail on what the settings mean, refer to “The BIS Trend Screen Display” in Section 3.3 and "Features and Capabilities" in Section 5.

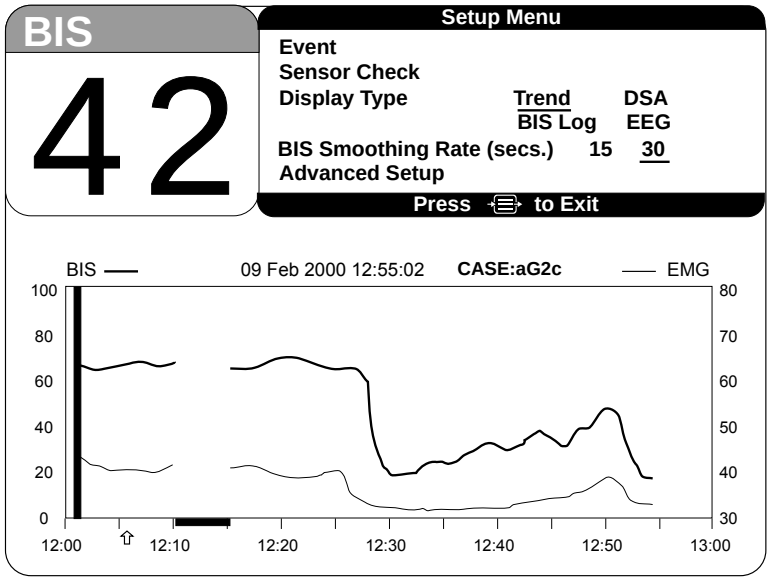


Figure 15 Main Screen with Setup Menu and Trend Display

When the Setup Menu appears, the first selection, "Event," is highlighted.

To move from one selection to another, use the up [↑] and down [↓] arrows to highlight the option you desire. Then follow the instructions below:

Event - This option is used during operation to mark a significant event on the screen display and printout.

To mark an event:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Press **[SELECT]** when **Event** is highlighted.

The event is immediately marked with an arrow on the time scale and the Setup Menu automatically exits to the Main Screen.

Sensor Check - Sensor impedance checks are initiated automatically when the PIC and sensor are attached to the DSC. You may initiate another check at any time by selecting this option.

To initiate the check:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Sensor Check**, using the [↑] or [↓] arrows.
3. Press **[SELECT].**

The check may be aborted at any time by pressing **[MENU/EXIT]**. When the check has been completed successfully, the screen will exit automatically. For details on the sensor check procedure, refer to "The Sensor Check" in Section 3.2.

Display Type – Allows the user to select the display in the graphic display region from four choices: Trend, DSA (Density Spectral Array), EEG, or BIS Log.

To change Display Type:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Display Type** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]** until the desired display type appears in reverse video.
4. Press the up [↑] or down [↓] arrows to move to the next menu item, or
5. Press **[MENU/EXIT]** to exit.

The system always defaults to the Trend display.

BIS Smoothing Rate (secs.) - The A-2000 offers two choices of smoothing rates over which the BIS value is averaged:

- 15 seconds (Provides increased responsiveness to state changes, such as induction or awakening). This is the default setting unless a BIS Extend Sensor is attached or the system is set to ICU mode.
- 30 seconds (Provides a smoother trend with decreased variability and sensitivity to artifact). This is the default setting when a BIS Extend Sensor is attached or when the system is set to ICU mode in the System Configuration Menu.

To change the BIS Smoothing Rate:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **BIS Smoothing Rate** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]** until the desired smoothing rate appears in reverse video.
4. Press the up [↑] or down [↓] arrows to move to the next menu item, or
5. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu.

Advanced Setup Menu

To display the Advanced Setup Menu:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.

3.4.3 The Advanced Setup Menu

The Advanced Setup Menu is used to select infrequently changed parameters. You may need to access the Advanced Setup Menu before using the system for the first time to set the date and time and to save any settings that were changed in the Setup Menu so they will not be lost when the monitor is powered off. You may exit the Advanced Menu at any time by pressing [MENU/EXIT]. Menu options are discussed below:

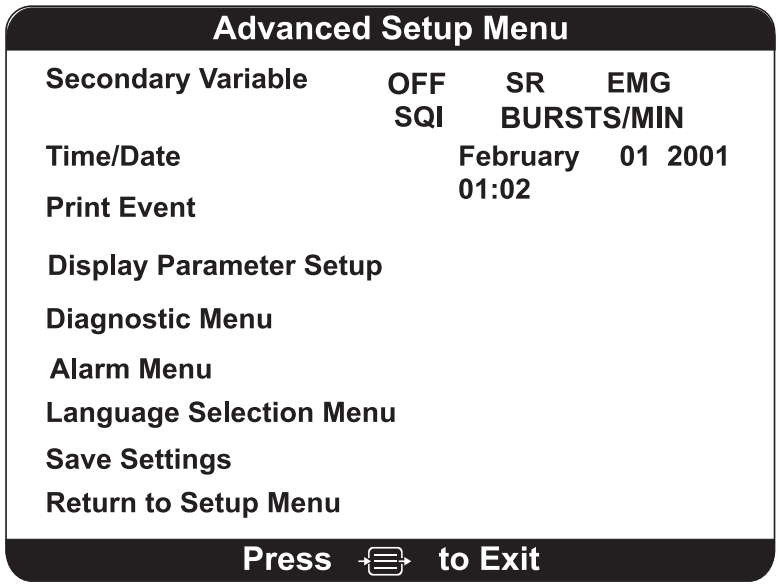


Figure 16 The Advanced Setup Menu

Secondary Variable - Adds a secondary trend variable to the Trend Graph:
Selecting "**SR**" will plot the suppression ratio.
Selecting "**EMG**" will plot electromyograph or high frequency signal detection.
Selecting "**SQI**" will plot the signal quality index.
Selecting "**BURSTS/MIN**" will plot the burst count. Note that this is available only when a BIS Extend sensor is attached to the PIC. If a BIS Extend sensor is not connected, this menu option does not appear.

To specify a secondary variable:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT].**
4. Highlight **Secondary Variable** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]** until the desired variable appears in reverse video.
6. Press the up [↑] or down [↓] arrows to move to the next menu item, or
7. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the "Save Settings" option in the Advanced Setup Menu.

Time/Date

To set the current time and date:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT**].
4. Highlight **Time/Date** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]** until the date or time value you wish to update appears in reverse video.
6. Use the up [↑] or down [↓] arrows to increase or decrease the values displayed.
7. Press **[SELECT]** to move to the next date or time value.
8. To save the date or time changes, press **[SELECT]** at the last Time/Date option (minutes). Pressing [Menu/Exit] before this last option aborts previous changes.
9. Press **[MENU/EXIT]** to exit from the Advanced Setup Menu.

Note:

The time/date is initially set for the Eastern Standard Time zone (USA). It will be necessary for you to change the time twice per year using the Time/Date feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

When a time/date is entered that is earlier than the current time/date in the monitor, all data memory will be erased. The prompt, "Clear Data Memory?" will appear to alert you of this. Press [SELECT] to confirm, or press [MENU/EXIT] to abort.

Print Event - Prints all available data on the most recent marked event.

To print an event:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Print Event** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.

Display Parameter Setup – Allows the user to turn filters OFF or ON, change the EEG sweep speed and amplitude settings, and change the default BIS Log recording interval.

To access the Display Parameter Setup screen:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.

The Display Parameter Setup options are discussed in section 3.4.3.

Diagnostic Menu

To display the Diagnostic Menu:

1. Press **[MENU/EXIT]** to access the Setup Menu.

2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Diagnostic Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.

Use of the Diagnostic Menu is covered in Section 7, "Diagnostics and Troubleshooting".

Alarm Menu – Allows the user to set the BIS high and low limit alarms.

To display the Alarm Menu:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Alarm Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.

The Alarm Menu options are discussed in section 3.4.6.

Language Selection Menu – The A-2000 is designed to support multiple languages.

To display the Language Selection Menu:
1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Language Selection Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.

The Language Selection Menu options are discussed in section 3.4.7.

Save Settings - The A-2000 monitor will always power up configured to settings that have been saved in memory.

To save the current configuration settings:
1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Save Settings** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]** to save setting changes. The current settings will be saved and the system will exit to the Main Screen.

Notes:

The Save Settings option is disabled when in Battery Backup-Low Power condition.

Impedance checking always returns to ON and Display Type returns to Trend after the monitor has been powered down.

Return to Setup Menu - Returns to the previous menu.

1. Press the up [↑] or down [↓] arrows to highlight **Return to Setup Menu.**
2. Press **[SELECT]** to re-display the Setup Menu.

3.4.4 Display Parameter Setup

This menu allows the user to view or change basic system parameters.

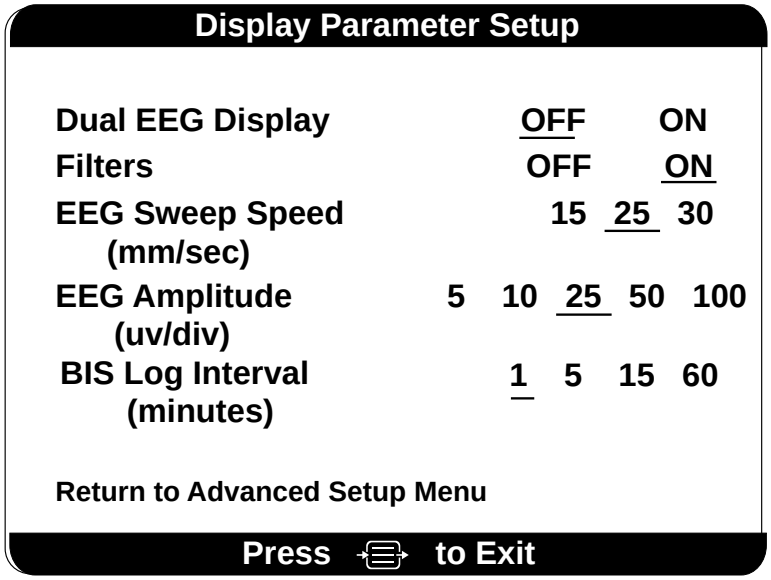

Display Parameter Setup
Dual EEG Display OFF ON
Filters OFF ON
EEG Sweep Speed (mm/sec) 15 25 30
EEG Amplitude (uv/div) 5 10 25 50 100
BIS Log Interval (minutes) 1 5 15 60
Return to Advanced Setup Menu
Press to Exit

Figure 17 The Display Parameter Setup screen

Dual EEG Display – This option displays only when a BIS Quatro or a BIS Extend sensor is connected. When Dual EEG Display is turned ON, the Signal Quality Region of the screen displays an additional channel of EEG that can be used for equipment troubleshooting purposes.

To display dual EEG waveform charts:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **Dual EEG Display** using the up [↑] or down [↓] arrows.
7. Press **[SELECT]** until ON appears in reverse video.
8. Press the up [↑] or down [↓] arrows to move to the next menu item, or
9. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu.

Filters - The A-2000 uses filters to screen out undesirable interference from the raw EEG signal display. If you prefer to observe the raw EEG without the filters, they may be turned off.

To turn the Filters off:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **Filters** using the up [↑] or down [↓] arrows.
7. Press **[SELECT]** until OFF appears in reverse video.
8. Press the up [↑] or down [↓] arrows to move to the next menu item, or
9. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the "Save Settings" option in the Advanced Setup Menu.

EEG Sweep Speed mm/sec – Allows the user to change the EEG sweep speed to 15, 25, or 30 mm/second.

To change the EEG Sweep Speed:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **EEG Sweep Speed** using the up [↑] or down [↓] arrows.
7. Press **[SELECT]** until the desired sweep speed appears in reverse video.
8. Press the up [↑] or down [↓] arrows to move to the next menu item, or
9. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the "Save Settings" option in the Advanced Setup Menu.

EEG Amplitude μv/div – (Display Type - EEG only) Allows the user to change the EEG amplitude to 5, 10, 25, 50, or 100 μV/div.

To change the EEG Amplitude:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **EEG Amplitude** using the up [↑] or down [↓] arrows.
7. Press **[SELECT]** until the desired EEG amplitude appears in reverse video.
8. Press the up [↑] or down [↓] arrows to move to the next menu item, or
9. Press **[MENU/EXIT]** to exit.

To permanently save this change, use the "Save Settings" option in the Advanced Setup Menu.

BIS Log Interval (minutes) – The interval at which the BIS values are reported in the BIS Log display can be set to 1, 5, 15, or 60 minutes.

To set the BIS Log Interval:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Display Parameter Setup** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **BIS Log Interval (minutes)** using the up [↑] or down [↓] arrows.
7. Press **[SELECT]** until the desired interval appears in reverse video.
8. Press the up [↑] or down [↓] arrows to move to the next menu item, or
9. Press **[MENU/EXIT]** to exit.

Alternatively, when BIS Log display is active, press the up [↑] or down [↓] arrows to increase or decrease the interval, respectively.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu. When ICU Mode is selected or when a BIS Extend sensor is attached, BIS Log interval is automatically set to 60 minutes.

Return to Advanced Setup Menu - Returns to the previous menu.

1. Press the up [↑] or down [↓] arrows to highlight **Return to Advanced Setup Menu.**
2. Press **[SELECT]** to re-display the Advanced Setup Menu.

3.4.5 The Diagnostic Menu

The Diagnostic Menu is covered in detail in Section 7.

3.4.6 Alarm Menu

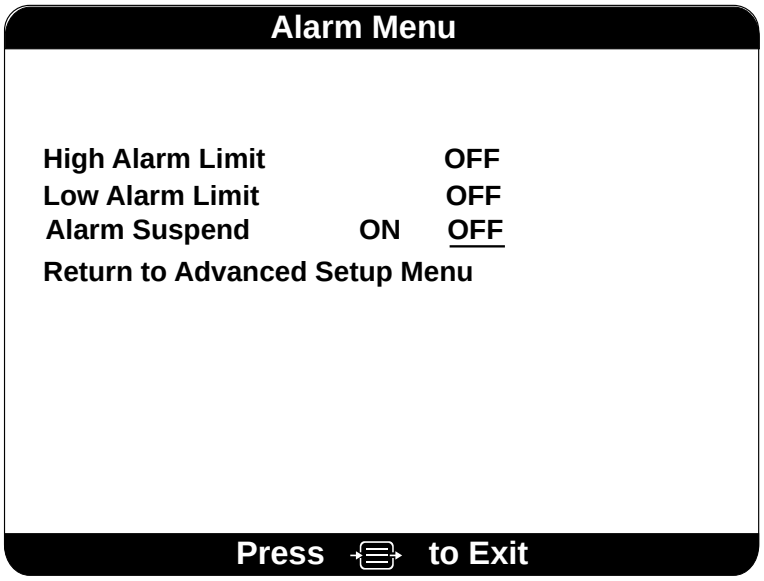


Figure 18 The Alarm Menu

High Alarm Limit - A high alarm limit may be set so that you are notified when the BIS number reaches a particular high level. If the BIS number reaches the high limit, the BIS number displayed on the screen will alternate from a solid display to an outlined display (when signal quality is good). If signal quality goes below 50, the outlined BIS number will blink on and off. The limit line shown on the graphic display will also blink. An alarm message appears and, if alarms have not been silenced, an audible alarm will sound.

To set the high alarm limit:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Alarm Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **High Alarm Limit.**
7. Press **[SELECT].**
8. Use the up [↑] or down [↓] arrows to increase or decrease the limit number.
9. Press **[SELECT]** to confirm the setting.
10. Press **[MENU/EXIT]** to exit the Alarm Menu.

Note:

Turning a limit alarm **OFF** differs from pressing the front panel [SILENCE] in that **OFF** disables audible and visible alarms for the BIS alarm limit only. The Alarm Silence key disables **all** audible alarms but does not disable visual alarms.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu.

Low Alarm Limit - A low alarm limit may be set so that you are notified when the BIS number reaches a particular low level. If the BIS number descends to the low limit, the BIS number displayed on the screen will alternate from a solid display and outlined display (when signal quality is good). If signal quality is below 50, the outlined BIS number will blink on and off. The limit line shown on the graphic display will also blink. An alarm message appears and, if alarms have not been silenced, an audible alarm will sound.

To set the low alarm limit:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Alarm Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **Low Alarm Limit.**
7. Press **[SELECT].**
8. Use the up [↑] or down [↓] arrows to increase or decrease the limit number.
9. Press **[SELECT]** to confirm the setting.
10. Press **[MENU/EXIT]** to exit the Alarm Menu.

Note:

Turning a limit alarm **OFF** differs from pressing the front panel [SILENCE] in that **OFF** disables audible and visible alarms for the BIS alarm limit only. The Alarm Silence key disables **all** audible alarms but does not disable visual alarms.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu.

Alarm Suspend – This option, when set to ON, automatically disables alarm silencing after 2 minutes. Alarm suspend is automatically activated when a BIS Extend Sensor is in use or when ICU mode is on.

To change the Alarm Silence button to suspend (rather than cancel) the audible alarm:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows.
3. Press **[SELECT]**.
4. Highlight **Alarm Menu** using the up [↑] or down [↓] arrows.
5. Press **[SELECT]**.
6. Highlight **Alarm Suspend.**
7. Press **[SELECT]** until ON appears in reverse video.
8. Press **[MENU/EXIT]** to exit the Alarm Menu.

To permanently save this change, use the “Save Settings” option in the Advanced Setup Menu.

Return to Advanced Setup Menu - Returns to the previous menu.

1. Press the up [↑] or down [↓] arrows to highlight **Return to Advanced Setup Menu.**
2. Press **[SELECT]** to re-display the Advanced Setup Menu.

3.4.7 Language Selection Menu

The A-2000 is designed to support multiple languages.

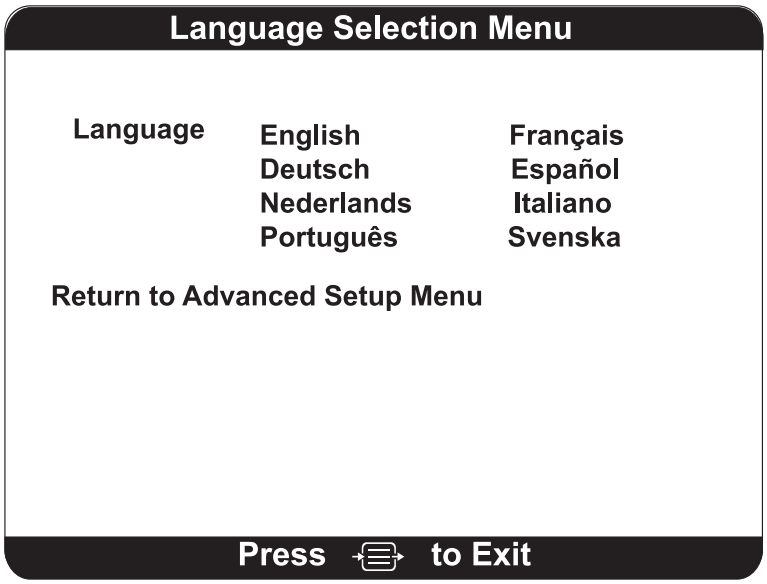


Figure 19 The Language Selection Menu

To change languages:

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Advanced Setup** using the up [↑] or down [↓] arrows, then press **[SELECT].**
3. Highlight **Language Selection Menu** using the up [↑] or down [↓] arrows.
4. Press **[SELECT]**. A new menu screen will display listing the language choices.
5. Press **[SELECT]** until the desired language is selected.
6. Use the up [↑] or down [↓] arrows to highlight **Return to Advanced Setup Menu** and press **[SELECT]**. This will redisplay the **Advanced Setup Menu** in the selected language.
7. To make sure that the selected language displays every time the monitor is turned on, use the arrows to highlight **Save Settings**, then press **[SELECT]** to save setting changes.

Return to Advanced Setup Menu - Returns to the previous menu.

1. Press the up [↑] or down [↓] arrows to highlight **Return to Advanced Setup Menu.**
2. Press **[SELECT]** to re-display the Advanced Setup Menu.

3.4.8 Sensor Data Display Screen And System Configuration Menu

The Sensor Data Display screen and System Configuration Menu are covered under the Diagnostic Menu in Section 7, "Diagnostics and Troubleshooting".

3.5 ALTERNATIVE DISPLAYS

Alternative screen displays can be requested in the Setup Menu. These displays are: DSA, EEG and BIS Log.

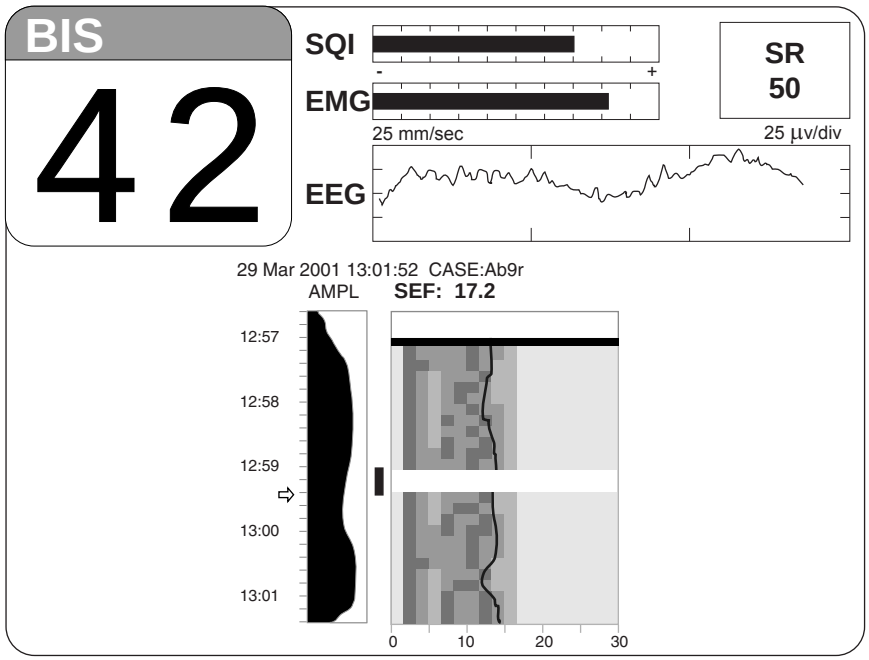


Figure 20 The Density Spectral Array (DSA) Display

3.5.1 The DSA Display:

The Density Spectral Array is displayed in the Graphic Display Region if the user has selected "Display Type DSA" in the Setup Menu.

Density Spectral Array **(DSA)** shows changes in the power spectrum distribution over time. The DSA is plotted using absolute spectra with a power scale of 0.0625 - 4 µV. The frequency scale is shown on the horizontal axis with a range from 0 - 30 Hz.

A **95% spectral edge marker** (actually three vertical lines: white/black/white) is superimposed on the DSA spectra and the current **spectral edge frequency value (SEF)** appears above the total power graph.

A graph of total power, indicating the strength of the signal based on a decibel (dB) scale, is shown beside the DSA and is labeled "**AMPL**"(amplitude).

A thick horizontal bar marks the **start of a case** at the time a new case is detected. A similar bar appears at the **end of a case** on the printer output. The monitor assumes that a case has ended if the DSC, the PIC, or the sensor have been disconnected for more than 10 minutes, or if the monitor has been turned off, then on.

During periods of poor signal quality (below 50), hatched **artifact bars** appear between the DSA and AMPL graphs. When signal quality is too low for BIS, these bars will show prominently as solid white and the DSA, total power, and spectral edge information will not be displayed.

Event markers may be added to the display by pressing [MENU/EXIT], then selecting [EVENT] from the Setup Menu. Event markers are shown as arrows next to the time scale markers.

When the user has set **alarm limits** in the Alarm Menu and these limits have been reached, the BIS number in the upper left corner of the screen will alternately display as a solid or outlined numeric character or blink depending on the signal quality, a message will appear in the Message Region of the screen, and a warning tone will sound (unless the [SILENCE] key has been pressed).

3.5.2 The EEG Display

This display is a larger version of the EEG waveform display in the signal quality region. Filtered EEG waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division (default). EEG filters can be turned off and the sweep speed and amplitude can be changed in the Display Parameter Setup screen.

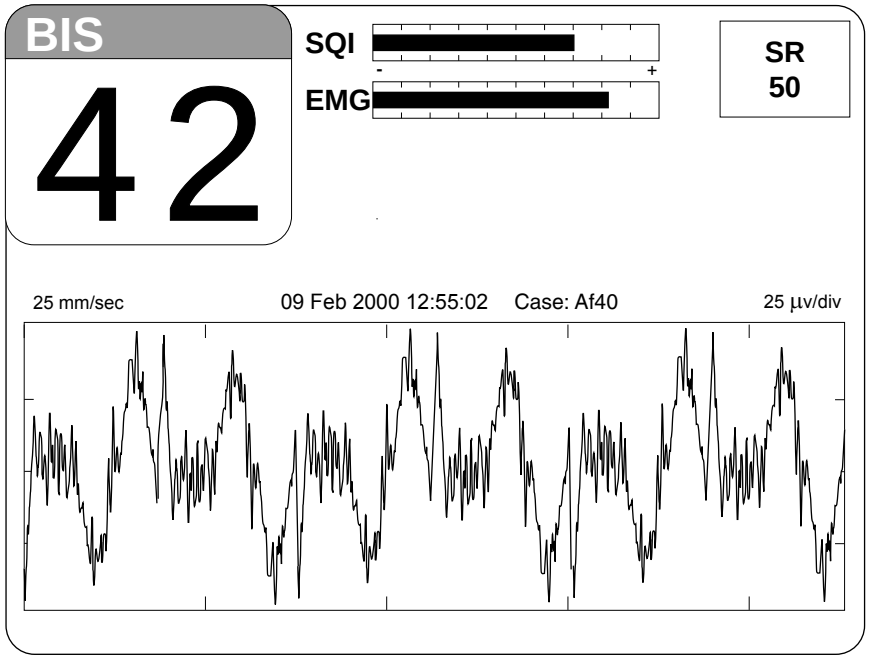


Figure 21 The EEG Display

3.5.3 The BIS Log Display

This display shows the BIS numeric values over time (up to 400 hours) and is updated continually as each value is calculated. Each line shows a one-minute sample of the minimum and maximum BIS values along with the average BIS, EMG, SR (Suppression Ratio), SQI (Signal Quality Index), and BURST (Burst Count) values during the previous one-minute period. Event markers (arrows) display when an event is noted. When signal quality is very low, BIS, SR and Burst Count values are not reported. Note that Burst Count is available only when a BIS Extend sensor is in use.

The time interval at which the BIS is reported can be set to 1, 5, 15, or 60 minutes in the Display Parameter screen. A 1-minute interval is recommended for a complete picture of the BIS over time.

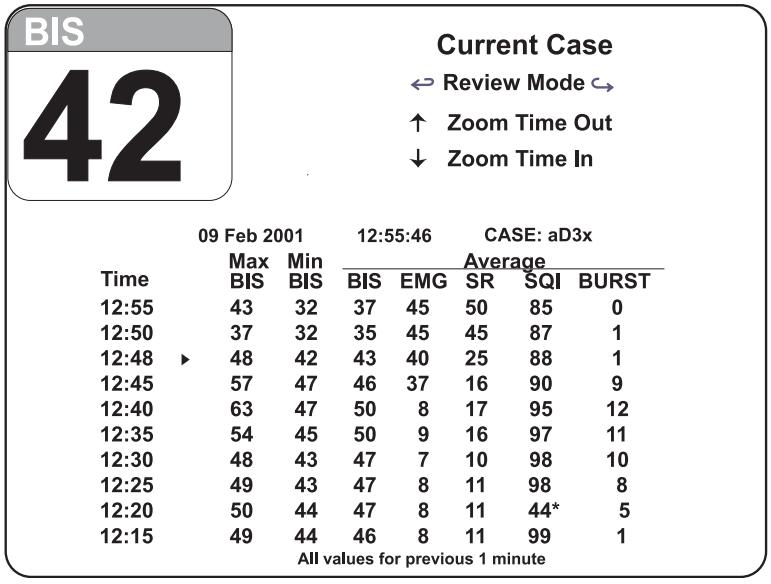


Figure 22 The BIS Log Display – Current Case

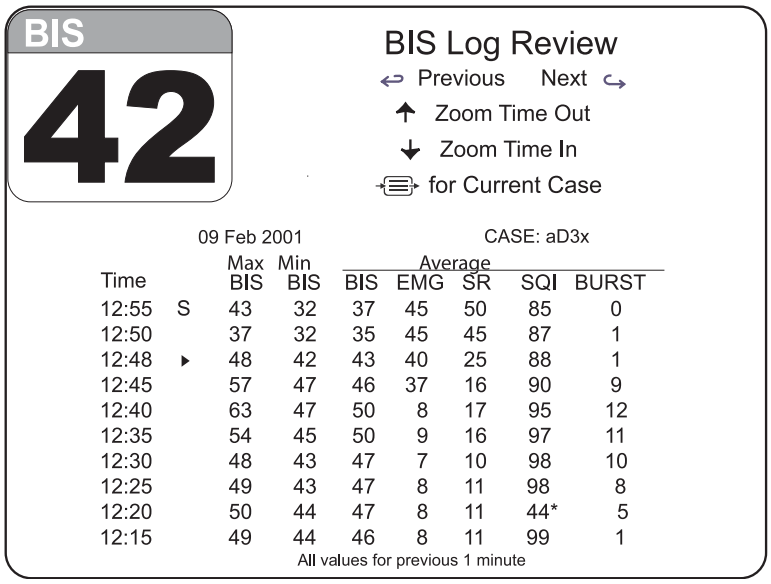


Figure 23 The BIS Log Display – Review Mode

Previous / Next: Use the left [←] arrow on the keypad to display the previous screen of data (earlier times). Use the right [→] arrow key to view the next screen of data (later times).

Zoom Time Out / In: Use the up [↑] arrow on the keypad to increase the time interval at which data are reported. Use the down [↓] arrow key to decrease the time interval.

Note:

Larger time intervals (5, 15, or 60 minutes) still report data from a one-minute sample. For example, in the figure above, 63 is the maximum BIS recorded from 12:39:01 through 12:40:00. A one-minute interval is recommended for continuous reporting of any changes in BIS values.

The one-minute sample containing a marked event is always displayed.

[MENU/EXIT]: In Current Case Mode, press the Menu/Exit key to display the Setup Menu. In Review Mode, press the Menu/Exit key to display the current case. When the Setup Menu is displayed, pressing the Menu/Exit key replaces the menu with the current case BIS Log screen instructions.

The **date, current time,** and **Case ID** are reported at the top of the current case BIS Log display. In Review Mode, the date and Case ID are displayed. For each time, the following information is displayed:

Time: The time at which the sample was taken. If an event was marked at that time, an event marker (→) is displayed at the next whole minute. (For example, in the figure above, an event that was marked at 12:47:12 is displayed on the 12:48 line.)

Max BIS: The maximum value for BIS during the previous minute. For example, if the time listed is 09:00, the maximum value recorded from 8:59:01 through 09:00:00 is displayed.

Min BIS: The minimum value for BIS during the previous minute.

Average BIS, EMG, SR, SQI, BURST: The average values for BIS, EMG, Suppression Ratio, Signal Quality Index and Burst Count during the previous minute. (Note that Burst Count is available only when a BIS Extend sensor is in use.) When signal quality is poor (below 50), an asterisk (*) is displayed next to the SQI value. When signal quality is very low, the BIS, SR, and Burst Count values are not reported.

The following indicators display with the appropriate line:
S – Start of case
E – End of case
T – The TIME/DATE has been changed in the Advanced Setup Menu.
→ – Event marked within previous minute.

Printed reports: When a printer is available, the BIS Log data for the displayed case may be printed by pressing the “PRINT” key.

The BIS numeric display for the current procedure will continue to be updated and parameter alarms will continue to be announced during BIS Log display.

3.6 REVIEWING STORED TREND DATA

Up to 11 hours of trend information may be viewed in Review Mode. (See Figure 24). To review information, press the left [←] or right [→] arrow key. The Signal Quality Region of the screen will indicate that you have entered Review Mode. Use the left [←] arrow to advance the display backward in time, or the right [→] arrow key to advance forward in time.

The Review Mode screen allows the user to select a secondary trend for display. Use the [SELECT] key to highlight the secondary trend you want to display.

When the printer is available, you may print screen data. First find the case you want to print using the REVIEW mode features then press the [PRINT] key on the printer. The currently displayed case will be printed. DSA and EEG display data are not stored and cannot be displayed.

Note:

When the system is using battery power, the printer is disabled to conserve power. Stored data are retained even after the battery is discharged.

The BIS numerical display for the current procedure will continue to be updated and parameter alarms will continue to be announced during Review Mode.

To return to the main display, press [MENU/EXIT].

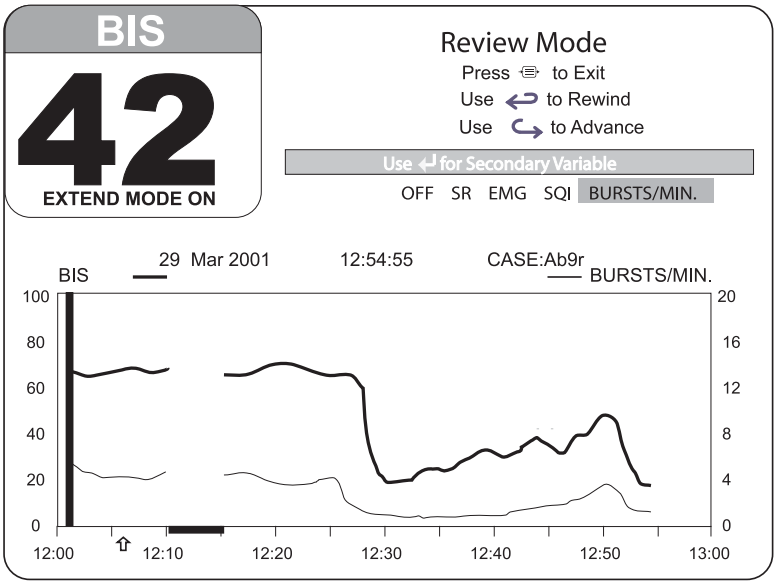


Figure 24 Main Screen with Trend Review

3.7 ENDING A CASE

When the case has finished:

- Disconnect the patient sensor from the PIC:
  Standard system: Grasp the connectors firmly and pull. DO NOT pull apart by the cable wires.
  BIS XP Platform/ XP Compatible: Press the release button on the connector and pull the connectors apart. DO NOT pull apart by the cable wires.
- Remove BIS Sensor from patient.
- Be sure to leave the PIC with the monitor so that it is not inadvertently discarded.
- If this is the last procedure of the day, press the button on the right side of the monitor to turn the power OFF.

WARNING!
SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

3.8 DATA TRANSFER

BIS values and other EEG data may be acquired from the monitor using the RS-232 serial port. Please contact Aspect Medical Systems for instructions. (See back cover for contact information.)

3.9 SOFTWARE UPDATES

The A-2000 monitor will automatically begin a software update if a software update device, attached to the serial port, is detected when the monitor power is turned on. Follow these steps to perform the update:

1. Before attempting an update, be sure to record your institution's saved settings, as they will be erased during the update procedure. If a printer is connected, access any menu and press [PRINT].
2. With the power off, connect the updating device to the Serial port at the rear of the monitor.
3. Turn the power on. As soon as the updating device is detected, the message "Software Update Device Detected" appears on the screen.
4. Press [SELECT] to initiate the update. (Press [MENU/EXIT] to skip update and the monitor will operate with the current software.) The update begins, and the message "Software Update In Progress. Do NOT Disconnect Software Update Device" appears. When the update is complete, the message "Software Update Successful" appears.
5. Disconnect software update device, then press [MENU/EXIT] to resume normal operation.
6. Re-enter your saved settings and save them in the Advanced Setup Menu.

Note:

When software is upgraded, all monitor configuration settings will be lost. Additionally, previously recorded data may be lost. Therefore, configuration settings and previous data should be recorded before the software update is performed.

SECTION 4
4 QUICK REFERENCE GUIDE

This “Quick Reference Guide” is intended only as an operating checklist for users already familiar with the A-2000 BIS Monitor. Do not proceed unless you have read the “Important Safety Precautions” (Section 1 of this manual).

BASIC OPERATION

If the A-2000 has already been installed, but has been turned off (after a previous surgery, for example), proceed as follows:

1. Verify that all power and other cables are connected properly.

    - The DSC’s long cable to the DSC port on the monitor.
    - The Patient Interface Cable to the short “DSC pigtail” extending from the DSC unit.

2. Press the button on the right side of the monitor to turn the power on. The system will initiate a self-test to ensure that all equipment is operating properly.

3. Prepare sensor site and place BIS Sensor on the patient in accordance with manufacturer’s instructions.

4. Using the attachment clip, secure the DSC to a convenient location near the patient’s head.

5. Insert the BIS Sensor tab into the PIC connector until fully engaged.

You are now ready to begin monitoring. A list of features and how to find them follows, for those familiar with operation. For detailed operating instructions and software configuration, read Sections 2 and 3. Current settings may be viewed at any time by viewing the appropriate menu. (See chart on next page.)

If you want to:	Do this:
• Mark an event • Initiate a sensor check • Change the display type • Change the BIS Smoothing Rate • Access the Advanced Setup Menu	• Press [MENU/EXIT] from the Main Screen to get to the **Setup Menu**. • Use the arrows to highlight your choice. • Press [SELECT].
• Change the secondary variable • Adjust the time or date • Print data from an event • Display the Parameter Setup • Access the Diagnostic Menu • Access the Alarm Menu • Access the Language Selection Menu • Save settings	• Press [MENU/EXIT] from the Main Screen to get to the Setup Menu, then select **Advanced Setup Menu**. • Use the arrows to highlight your choice. • Press [SELECT].
• Display a second channel of EEG (BIS Quatro and BIS Extend sensors only) • Turn the EEG filters OFF • Change the EEG sweep speed • Change the EEG amplitude • Change the default BIS Log interval	• Press [MENU/EXIT] from the Main Screen to get to the Setup Menu, then select Advanced Menu. • From the Advanced Menu, select **Display Parameter Setup**. • Use the arrows to highlight your choice • Press [SELECT].
• Test the DSC • Test the screen display • View sensor data • Clear data • Display diagnostic codes • Disable continuous impedance check • Access the System Configuration Menu • Find the software revision number, serial number, or other data	• Press [MENU/EXIT] from the Main Screen to get to the Setup Menu, then select Advanced Setup Menu. • From the Advanced Setup Menu, select the **Diagnostic Menu**. • Use the arrows to highlight your choice • Press [SELECT].
• Set BIS limit alarms • Change the Alarm Silence button to suspend alarm silence after 2 minutes.	• Press [MENU/EXIT] from the Main Screen to get to the Setup Menu, then select Advanced Setup Menu. • From the Advanced Setup Menu, select the **Alarm Menu**. • Use the arrows to highlight your choice • Press [SELECT].

If you want to:	Do this:
• Change the serial port protocol • Enable / disable extended memory recording • Change the monitor to ICU mode	• Press [MENU/EXIT] from the Main Screen to get to the Setup Menu, then select Advanced Setup Menu. • From the Advanced Setup Menu, select the Diagnostic Menu. • From the Diagnostic Menu, select the **System Configuration Menu**. • Use the arrows to highlight your choice • Press [SELECT].

SECTION 5
5 FEATURES AND CAPABILITIES

INTRODUCTION

This section includes:

- How the A-2000 BIS Monitoring System works
- Display Configurations
- Other System Features

5.1 HOW THE A-2000 MONITORING SYSTEM WORKS

A sensor placed on the patient's head transmits EEG signals to the Digital Signal Converter. The DSC amplifies and digitizes these signals, then sends them to the monitor. The monitor software filters the data, analyzes it for artifact, and processes it using digital signal processing techniques. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

A list of the processed variables and a description of each is provided in Appendix I. These data are displayed on the screen according to the preferences set by the user in the Setup Menus.

5.2 SYSTEM FEATURES

5.2.1 Bispectral Index (BIS)

Range = 0 – 100

The Bispectral Index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. BIS was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain. BIS is displayed as a number in the upper left corner of the screen and is plotted over time in the Graphic Display Region.

5.2.2 Signal Quality Index (SQI)

Range = 0 – 100

The SQI is a measure of the signal quality for the EEG channel source and is calculated based on impedance data, artifact, and other variables. It is displayed in the form of a simple bar graph located at the top right corner of the display screen. It is optimal when the SQI bar extends all the way to the right. SQI may also be plotted over time as a secondary variable on the trend graph.

5.2.3 Electromyograph (EMG) Indicator

EMG 70-110 Hz Bar Graph Display Range 30 – 55dB

The power (in decibels) in the frequency range 70-110 Hz is labeled “EMG.” This frequency range contains power from muscle activity (i.e., electromyography or “EMG”) as well as power from other high-frequency artifacts. The EMG bar graph displays this activity. It is optimal when the bar is empty.

5.2.4 Electroencephalogram (EEG) Waveform Display

Sweep speed – 25 mm/sec Amplitude – 25 μV/ division

Filtered EEG waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division. Filters may be turned off in the Display Parameters screen. The sweep speed can be changed to 15, 25 or 30 mm/sec and the amplitude to 5, 10, 25, 50, 100 μV/ division.

5.2.5 Filters

ON (2 – 70 Hz with notch) or OFF (.25 – 100 Hz)

The A-2000 uses filters to screen out undesirable interference from the raw EEG signal display. If you prefer to observe the raw EEG without the filters, they may be turned off. The Notch filter includes filters for both 50 and 60 Hz. Filters ON or OFF does not affect processing of the Trend variables (i.e., BIS, EMG, SR, and SQI), but will affect the DSA display. Viewing the EEG signal without filters may aid in troubleshooting signal problems.

5.2.6 Suppression Ratio (SR)

Range = 0 – 100%

Suppression ratio is a calculated parameter to give the user an indication when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state. For example: SR=11 (isoelectric over 11% of the last 63 second review). The SR is displayed in the upper right corner of the screen. When SR reaches 100%, the message “Isoelectric EEG Detected” will notify the user. Suppression ratio can be plotted over time as a secondary trend in the Graphic Display Region.

5.2.7 Burst Count (BURSTS/MIN)

Range = 0-20

Burst Count is an alternative method of quantifying suppression, available only when a BIS Extend sensor is in use. The system defines a “burst” as a short period of EEG activity, preceded and followed by periods of inactivity. Computed from suppression data, it is reported as the number of EEG bursts per minute. The burst count is displayed in the upper right corner of the screen, under the suppression ratio, and may also be graphed as a secondary variable in the Graphic Display Region. When the signal quality is low (SQI less than 15) or when the suppression ratio is less than 5, the burst count is not displayed.

5.2.8 Density Spectral Array (DSA)

The Density Spectral Array (DSA) shows changes in the power spectrum distribution over time. Brighter points on the display correspond to greater power content (on the printout this is reversed, i.e., darker points correspond to greater power content). The total amplitude of the signal is shown by an amplitude bar (based on a decibel scale) that is displayed beside the DSA plot. A spectral edge frequency number and the spectral edge line show the frequency at which 95% of the total power lies below it and 5% lies above it.

5.2.9 BIS Log Display

This display shows the BIS numeric values over time and is updated continually as each value is calculated. Each line shows a one-minute sample of the minimum and maximum BIS values along with the average BIS, EMG, SR (Suppression Ratio), SQI (Signal Quality Index), and Burst Count values during the one-minute period. Event markers (arrows) display when an event is noted. When signal quality is low, an asterisk (*) appears at the end of the line. If signal quality is very low, BIS, SR, and Burst Count values are not reported. If the Suppression Ratio is below 5, BURST is not reported. Note that Burst Count is only reported when a BIS Extend sensor is in use.

The time interval at which the BIS is reported can be set to 1, 5, 15, or 60 minutes in the Display Parameter screen. The default value of 1 minute is recommended for a complete picture of the BIS over time.

5.2.10 Artifact Detection

The A-2000 is designed to provide only highly reliable data. It is therefore programmed not to display data that has been corrupted by artifact. Artifact bars appear on the display whenever this occurs.

5.2.11 Event Markers

Events may be marked on the Trend or DSA display using the Setup Menu. Events are shown as arrows on the time scale of the Trend display, as well as the BIS Log display.

5.2.12 Start and End of Case Bars / Case ID

The A-2000 draws a thick line to mark the start of a new case and assigns a unique Case ID number that displays at the top of the Graphic Display Region. If the DSC, the PIC, or the sensor have been disconnected for more than 10 minutes, or when the monitor is turned off, then on, the case is marked as ended. An end of case line marker is shown in Review Mode and on printouts.

5.2.13 Limit Alarms

The A-2000 alerts you to a BIS alarm limit violation by flashing the BIS number and sounding a tone. You can silence the audible alarms by pressing the Alarm Silence key. Alarm limits are displayed in the graphic display area of the screen and may be changed in the Alarm Menu.

5.2.14 BIS Trend Smoothing

The A-2000 offers two choices of smoothing rates over which the BIS value is averaged:

- 15 seconds (Provides increased responsiveness to state changes, such as induction or awakening). This is the default setting except when a BIS Extend Sensor is attached or the system is set to ICU mode.
- 30 seconds (Provides a smoother trend with decreased variability and sensitivity to artifact). This is the default setting when a BIS Extend Sensor is attached or the system is set to ICU mode.

5.2.15 Event Printing

When EVENT is selected from the Setup Menu, EEG and processed data from the previous ten minutes of the case are saved in memory. When a printer is available, you may print portions of this data by selecting “Print Event” from the Advanced Setup Menu.

If the case containing the marked event is still in memory, the printout includes:

- All available trend data for the case
- Up to 30 seconds of EEG data recorded prior to marking the event
- A-2000 setup and configuration information.

If the case is no longer in memory, the printout includes:

- Up to 10 minutes of trend data collected prior to marking the event
- Up to 30 seconds of EEG data
- A-2000 setup and configuration information.

Note that only one event is saved in memory. Pressing the Event marker a second time overwrites the previous record.

5.2.16 Languages

The A-2000 is designed to display multiple languages, including English, German, Dutch, Portuguese, French, Spanish, Italian and Swedish. When the language has been changed in the Language Selection Menu, all screens display in the selected language.

5.2.17 Time/Date and Clear Data Memory

The current time and date can be set in the Advanced Setup Menu. When the time/date is changed to an earlier time, the system prompts the user to clear the data memory to avoid duplicate time entries.

5.2.18 Sensor Data Display (BIS XP Platform only)

When the Sensor Data Display is selected from the Diagnostic Menu, the following sensor data are displayed: lot code, serial number, sensor type, expiration date, whether the sensor was used for more than 5 minutes or not, and the number of times the same sensor was connected. The date and time of each connection is also displayed.

5.2.19 ICU Mode / Extend Mode

When the ICU Mode is turned on in the System Configuration Menu, the BIS smoothing rate is set to 30 seconds, Alarm Suspend is set to ON (so that alarms will only be silenced for 2 minutes), and the BIS Log interval is set to 60 minutes. When a BIS Extend Sensor is attached, the system automatically switches to these same settings.

5.2.20 System Self-Checks

The A-2000 monitor has several self-checking features to ensure that the system is operating properly. These include:

System Check
Initiated when the unit is powered on, this test makes certain that system software and hardware components are functioning properly.

Equipment and Connection Checks
The system checks continuously to be sure that the DSC, the PIC, and patient sensors are operating properly and have not become disconnected.

DSC Self-Test
The Digital Signal Converter self-test is a thorough test of the entire signal processing chain including the signal processing computers. The DSC self-test may be initiated in the Diagnostic Menu (see Section 7).

Display Self-Test
This self-test, also found in the Diagnostic Menu (see Section 7), performs a thorough test of the screen display functions. This test will not be performed while the monitor is operating on battery backup.

Sensor Integrity Check (BIS XP Platform only)
This test begins each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

Impedance Check (Sensor Check)
Electrode impedance is tested when the DSC and PIC are connected and is monitored continuously unless the user has turned impedance checking off in the Diagnostic Menu.

Caution:
Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment, e.g., evoked potential monitors.

Diagnostics
The A-2000 provides diagnostic codes to assist the user in tracing the source of any problems that may occur. Codes are displayed in the right corner of the message region only if the user has selected them in the Diagnostic Menu.

5.2.21 Data Memory

The monitor stores recorded trend data with time and date of acquisition. The duration of trend data stored is approximately 24-25 hours. Trend memory can be viewed on the screen in 1-hour segments using the Review arrow keys [←] [→] to scroll through memory.

BIS Log information is stored for 400 hours of active monitoring.

Ten minutes of data leading up to the most recent marked event is saved and can be printed by selecting “Print Event” from the Advanced Setup Menu.

Sensor information is also stored and can be viewed in the Sensor Data Display screen.

When the memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the battery has been discharged and remains when the monitor is in the power off condition.

5.2.22 Saved Settings

After power up, your instrument will revert to user settings that are set up, then saved in the Advanced Setup Menu.

5.2.23 Battery Operation

In the event of a power failure or interruption of power during a procedure, the monitor automatically switches to back-up battery operation. During battery operation, a BATTERY symbol appears in the BIS numeric region of the display. A fully charged battery will provide a minimum 20 minutes of operation. The thermal printer is disabled during battery operation. The battery symbol blinks to alert the user when only a few minutes of back-up power remain. The Save Settings feature is disabled when the battery symbol is blinking. Battery recharge time is approximately 4 hours with the monitor ON.

Note:

The monitor must be powered ON to recharge the battery.

5.2.24 Data Transfer and Software Updates

Data may be transferred to and from the A-2000 monitor using the Serial port on the back panel. Request the Aspect A-2000 Serial Port Specification (P/N 070-0017) for a complete description of the protocols. This port is also used to easily upgrade system software.

WARNINGS!

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 601-1 AND/OR IEC 601-1-1 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC601-1-1 LIMIT.

Note:

When software is upgraded, all monitor configuration settings will be lost. Additionally, previously recorded data may be lost. Therefore, configuration settings and previous data should be recorded before the software update is performed.

5.2.25 Printed Reports

A printer port connector allows connection to the Aspect A-2000 Printer.

SECTION 6
6 PREVENTIVE MAINTENANCE, CARE AND CLEANING

INTRODUCTION

This section describes:

- Care and cleaning procedures
- Routine maintenance.

6.1 CARE AND CLEANING

WARNING!
UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

Cleaning the Monitor and Digital Signal Converter
Clean any spillage of blood or solutions on either the monitor or Digital Signal Converter as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector end with alcohol and allow to dry completely. Residual moisture inside the connector may affect DSC performance.

Disinfecting the Monitor and Digital Signal Converter
Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes).

After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the PIC and DSC pigtail connector ends with alcohol and allow to dry completely.

WARNING!
WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA) AS HAZARDOUS GASES MAY RESULT.

Caution:

Do not autoclave the Digital Signal Converter or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

Cleaning the Monitor Display

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

6.2 ROUTINE MAINTENANCE

The A-2000 monitor is designed so that no periodic adjustment or calibration is required.

Checking the Battery

Check the battery periodically by operating an A-2000 that has been disconnected from the wall socket and that has been charging the battery for at least 4 hours. If the A-2000 fails to operate reliably from the battery for 20 minutes, battery replacement is required.

WARNING!

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

GROUND WIRE LEAKAGE CURRENT MUST BE CHECKED WHENEVER INSTRUMENT CASE IS OPENED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN.

Caution:

Check the battery periodically by operating an A-2000 that has been disconnected from the wall socket and that has been charging the battery for at least four hours. After long periods of storage (e.g., greater than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the A-2000 fails to operate reliably from the battery for twenty minutes, battery replacement is required.

The A-2000 contains an internal Nickel-Metal-Hydride battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for servicing of battery.

Checking Leakage Current
Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each A-2000 BIS Monitor is carefully checked at the factory to verify that leakage current meets the UL2601 and IEC601-1 safety standards.

The A-2000 should be checked routinely for leakage current at least once a year. Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and after every time the monitor case has been opened.

Keep in mind that liquids such as saline and Ringer's as well as blood are all excellent conductors of electricity. Avoid touching any part of the system with wet hands. Always work with clean, dry hands.

WARNING!
ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS. WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST BEFORE FURTHER USE.

6.3 FUSE REPLACEMENT

The A-2000 contains two inline fuses (1.25A, 250V, 5x20mm Aspect P/N 430-0006) within the AC power input module located at the rear of the monitor. In the unlikely event that a fuse needs to be replaced, one can access these fuses as follows:

1. The fuse holder is part of the AC power input module on the rear of the monitor and is located just above the power cord input connector.
2. Disconnect the AC power cord from the wall socket and from the rear of the monitor.
3. Locate the plastic locking tabs securing the fuse holder in place.
4. Insert the tip of a ball point pen or similar tool, into the slots provided to release the plastic locking tabs allowing the fuse holder to spring out of its locked position.
5. Remove and replace both fuses.
6. To re-install the fuse holder, simply insert the fuse holder and press in with finger until the plastic locking tabs engage, securing the fuse holder in place.

WARNING!
REPLACE FUSES ONLY WITH ONE OF THE FOLLOWING PARTS:
Aspect P/N 430-0006, 1.25 Amps, 250V, 5x20mm
Littelfuse 217 Series, 1.25 Amps, 250V, 5x20mm
Wickmann 193 Series, 1.25 Amps, 250V, 5x20mm

ALWAYS REPLACE BOTH FUSES TOGETHER, EVEN IF ONLY ONE HAS FAILED.

6.4 SYSTEM CHECKOUT

1. Secure all components.
   - Monitor with power cable
   - DSC
   - PIC (Patient interface cable, connects DSC to patient)
   - BIS Sensor or test sensor.

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.

3. Power up monitor by pressing power switch (right lower side of case).

- Verify beep tone as power switch is activated.
- Verify fan (rear case wall) moves air outward.
- Verify all power on self-tests complete successfully (approx. 30 seconds).
- Verify next screen says 'CONNECT DSC CABLE TO FRONT OF MONITOR.'

4. Connect DSC with PIC and Sensor.
   - Verify DSC test completes.
   - Verify SENSOR CHECK screen displays.

5. Exit from SENSOR CHECK screen by passing impedance check or by exiting with MENU/EXIT key.

6. Disconnect power cord from rear of monitor.

   - Verify 'OPERATING ON BATTERY BACKUP (E33)' is displayed.
   - Verify battery icon displays in BIS banner.

7. Reconnect power cord.
- Verify battery icon is not displayed in BIS banner.
- Verify 'OPERATING ON BATTERY BACKUP (E33)' is not displayed.

8. Do keyboard checkout:
   - Press SILENCE key — Verify icon shows at BIS banner.
   - Press ARROW BACK key — Verify REVIEW MODE screen displays.
   - Press MENU/EXIT key — Verify REVIEW MODE screen exits.
   - Press ARROW AHEAD key — Verify REVIEW MODE screen displays.
   - Press MENU/EXIT key — Verify REVIEW MODE screen exits.
   - Press MENU/EXIT key — Verify Setup menu displays.
   - Press UP ARROW key — Verify highlight bar moves up with each press.
   - Press DOWN ARROW key — Verify highlight bar moves down with each press.
   - Press SELECT key — Verify that highlighted menu line is selected.
   - Press MENU/EXIT until BIS banner is displayed.

9. End of checkout.

6.5 TECHNICAL DOCUMENTATION

The A-2000 BIS Monitoring System is designed and manufactured using state-of-the-art components and manufacturing processes. Field repair or customer repairs are therefore limited by design to replacement of major component assemblies such as the Patient Interface Cable (PIC), Digital Signal Converter (DSC), or the A-2000 Monitor itself.

This A-2000 Operator Manual contains the maintenance and diagnostic troubleshooting information necessary for customer qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal components of the A-2000.

6.6 INSTRUMENT IDENTIFICATION

A-2000 Monitor
Monitor identification information is permanently marked on the rear panel. This information includes instrument model and serial numbers, patent numbers, power ratings, cautions, and the Aspect Medical Systems' shipping address.

A-2000 Digital Signal Converter
The A-2000 Digital Signal Converter identification information is permanently marked on the rear panel of the Digital Signal Converter. The information includes instrument model and serial numbers, patent numbers, cautions, and the Aspect Medical Systems' shipping address.

Software Revision Numbers
Software revision numbers are displayed in the Diagnostic Menu.

SECTION 7
7 DIAGNOSTICS AND TROUBLESHOOTING

INTRODUCTION

This section details:

- The Diagnostic Menu
- System and patient messages and appropriate operator actions
- What to do if the A-2000 requires service.

7.1 THE DIAGNOSTIC MENU

The Diagnostic Menu is designed to help you trace the source of problems you may be experiencing with the A-2000 system. It may be accessed by selecting “Advanced Setup” from the Setup Menu, then selecting “Diagnostic Menu.”

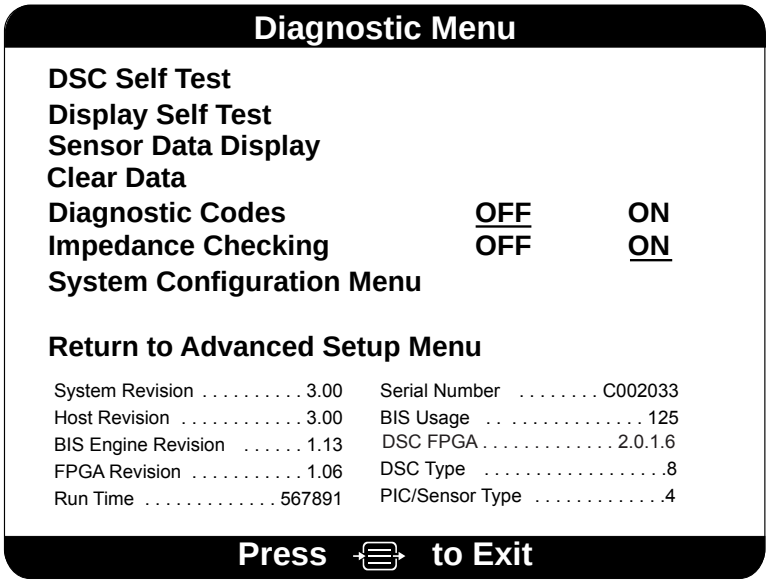

Diagnostic Menu
DSC Self Test
Display Self Test
Sensor Data Display
Clear Data
Diagnostic Codes OFF ON
Impedance Checking OFF ON
System Configuration Menu
Return to Advanced Setup Menu
System Revision 3.00
Host Revision 3.00
BIS Engine Revision 1.13
FPGA Revision 1.06
Run Time 567891
Serial Number C002033
BIS Usage 125
DSC FPGA 2.0.1.6
DSC Type 8
PIC/Sensor Type 4
Press to Exit

Figure 25 The Diagnostic Menu

The Diagnostic Menu Data Display
Important data are displayed in the Diagnostic Menu, which you may need to know if you call with a service question. This includes: System Revision, Host Revision, BIS Engine Revision, FPGA Firmware Revision, Run Time, Serial Number, BIS Usage Counter, DSC Type, and PIC/Sensor Type. These numbers will be updated if any software updates are performed, or each time a new DSC or sensor is attached. The BIS Usage Counter increments whenever a PIC or Sensor is connected. The Run Time shows the monitor operating time in seconds.

7.1.1 DSC Self-Test
The Digital Signal Converter self-test is a thorough test of the entire signal processing chain including the signal processing computers. Selecting this item will initiate an extensive DSC test and printout (if a printer is connected). The DSC test reports PASS/FAIL status, noise, high-pass blocked, high-pass normal and gain values. If any of the self-tests fail, notify your Biomedical Engineering Department or your Aspect Medical Systems service representative. See Section 7.3 “What to do if the A-2000 Requires Service.”

7.1.2 Display Self-Test
To test the screen display, this test may be selected from the Diagnostic Menu. The user is instructed to press [SELECT] to start the test. The test may be ended at any time by pressing [MENU/EXIT]. This test will not be performed when the unit is on battery backup.

7.1.3 Sensor Data Display (BIS XP Platform only)
Select this item to display information about sensors that have been used on the A-2000 monitor. If you are experiencing problems with the sensor, check this screen and note the appropriate sensor information before contacting Aspect. The latest sensor used will display first. Information about other sensors may be displayed by using the up and down arrows to scroll through the sensor database. The following data are displayed: the lot code, serial number, sensor type, expiration date, whether the sensor was used for more than 5 minutes or not, and the number of times the same sensor was connected. The date and time of each connection are also displayed.

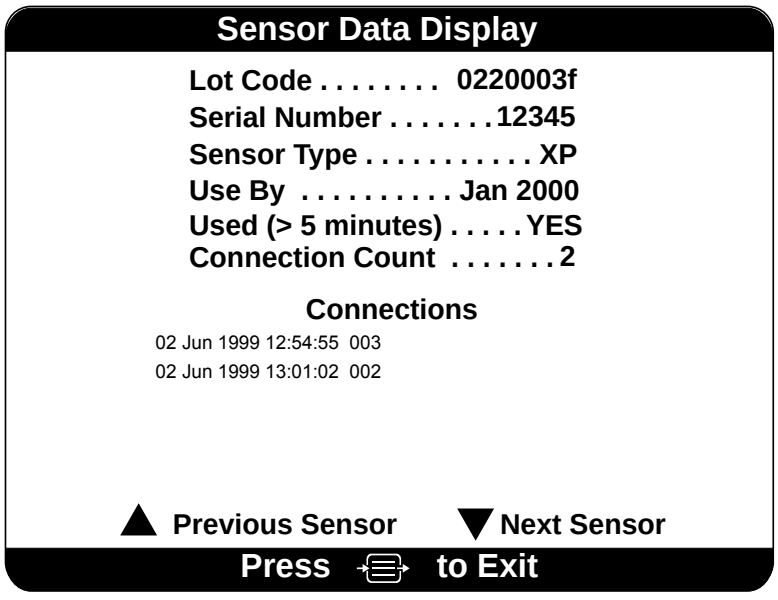

Sensor Data Display
Lot Code 0220003f
Serial Number 12345
Sensor Type . . . . . XP
Use By . . . . . Jan 2000
Used (> 5 minutes) . . . . . YES
Connection Count 2
Connections
02 Jun 1999 12:54:55 003
02 Jun 1999 13:01:02 002
Previous Sensor
Next Sensor
Press to Exit

Figure 26 Sensor Data Display

7.1.4 Clear Data

This option clears all data from the system memory and starts a new case.

1. Press **[MENU/EXIT]** to access the Setup Menu.
2. Highlight **Clear Data**, using the [↑] or [↓] arrows.
3. Press **[SELECT]**. The system will respond with the message; "**Clear Data Memory?**"
4. Press **[SELECT]** to confirm, or press **[MENU/EXIT]** to cancel.

7.1.5 Diagnostic Codes

If you are experiencing problems with the A-2000 monitor, you may wish to turn the Diagnostic Codes ON so that numerical diagnostic values will be displayed in the Message Region of the screen. To do so, press [SELECT] when "Diagnostic Codes" is highlighted until "ON" appears in reverse video. Then use the arrows to go to the next option, or press [MENU/EXIT] to exit.

7.1.6 Impedance Checking

The A-2000 continually checks impedance levels during a procedure by generating a 128 Hz test signal. Occasionally this signal may interfere with other equipment. If this becomes a problem, you may turn off the continuous impedance checking by pressing the [SELECT] key until the "Impedance Checking –OFF" appears in reverse video. Then use the arrows to go to the next option, or press [MENU/EXIT] to exit. Impedance levels will still be tested at startup, but once they pass, they will not be tested again until a new case is begun.

Note:

Turning off continuous impedance checking will not be saved by the "Save Current Settings" feature. The next time the monitor is powered on, the monitor will re-enable continuous impedance checking.

7.1.7 System Configuration Menu

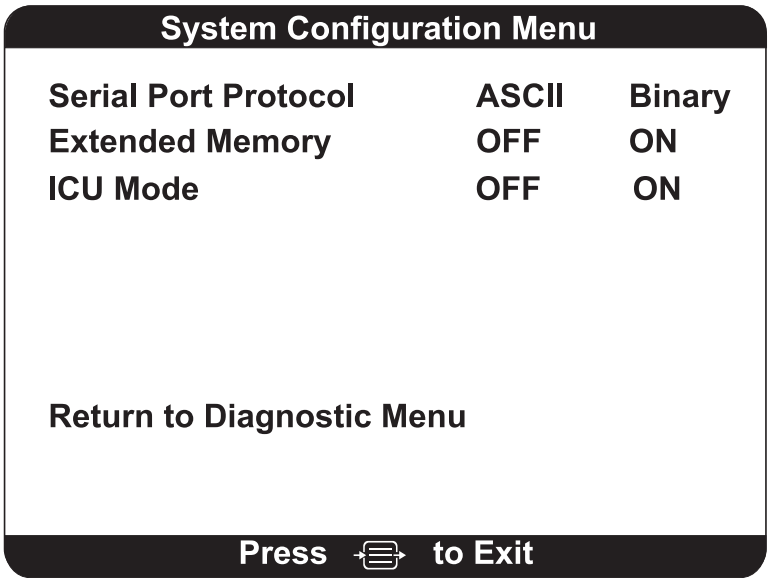


Figure 27 The System Configuration Menu

Serial Port Protocol
Data may be transmitted from the serial port in two formats, ASCII and BINARY, depending upon which option is selected. To select an option, use the down arrow when the Diagnostic Menu is displayed until Serial Port Protocol is highlighted. Press [SELECT] until the desired protocol appears in reverse video. Then use the arrows to go to the next option, or press [MENU/EXIT] to exit. If a user is interested in acquiring data from the serial port, consult with an Aspect representative and request the Aspect A-2000 Serial Port Specification (P/N 070-0017). See back cover for contact information.

Extended Memory
The extended memory feature records and stores into memory BIS, EMG, SR, SQI, and Burst/Min values at one-minute intervals for a period of up to 409 hours of active monitoring. These values are accessible to the user via the BIS Log display. This information will remain in memory (until overwritten) and can also be retrieved with the assistance of qualified Aspect personnel via the external serial port, subject to appropriate provider consents. The customer retains rights to access this data and Aspect will not access the data without permission of the customer. Occasionally, Aspect may seek such permission to evaluate performance of the A-2000 monitor and to provide user feedback.

ICU Mode / Extend Mode
When the ICU mode is set to ON, the BIS smoothing rate is set to 30 seconds, Alarm Suspend is set to ON (so that alarms will only be silenced for 2 minutes), and the BIS Log interval is set to 60 minutes. These individual parameters can be reset to other values independently. When a BIS Extend sensor is attached, the system automatically switches to these same settings.

Return to Advanced Setup Menu
Press [SELECT] when this option is highlighted to return to the previous menu. To return to the Main Screen, press [MENU/EXIT].

7.2 SYSTEM ERROR MESSAGE ALARMS

Equipment alarm messages, lead connection, and patient condition alarms (i.e., EEG isoelectric condition) will appear in the message region of the display and an alarm sequence (two tones, high/low, that sounds like “Uh-oh”) will sound when any of the following conditions occur: Digital Signal Converter becomes disconnected, patient electrode leads come off, electrode impedance check fails, or Digital Signal Converter has a power fault. Error messages and the corresponding operator action required for these and other error conditions are listed below:

A-2000 Error Messages and Operator Action

E01 Message: **DSC Not Connected**
Operator Action: Check that the blue cable from the DSC is connected to the front panel of the monitor. If connected, and the DSC doesn’t work, the DSC or monitor may require service.

E02 Message: **DSC Overcurrent**
Operator Action: The run-time diagnostics tries up to three times to clear this error condition. If it doesn’t work, the DSC or monitor may require service.

E03 Message: **DSC Power Regulation**
Operator Action: The run-time diagnostics checks three times for this error condition. This indicates that the DSC may require service.

E04, E05, E06, E07, E08 Message: **DSC Error**
Operator Action: The DSC is not communicating or operating properly. This may occur during the use of electrocautery devices. If the message persists, the monitor or DSC may require service.

E09 Message: **DSC Shut Down**
Operator Action: Too many fatal errors (overcurrent, voltage regulation) have occurred with this DSC and the monitor has stopped trying to get it to work. Turn the monitor off, then on to try again. If this problem persists, the DSC and/or monitor require service.

E10 Message: **Illegal DSC Type**
Operator Action: An unrecognized DSC has been connected to the monitor. Connect correct DSC. If error persists, the DSC and/or the monitor may require service.

E11 Message: **DSC Failed Self-Test**
Operator Action: The DSC has failed either the noise test or gain test performed at startup. The DSC and/or the monitor may require service.

E12 Message: **Illegal Sensor Type**
Operator Action: An unrecognized Patient Interface Cable/Sensor has been connected to the DSC. Make sure that the PIC connector is clean and dry. (See Section 6.1). The PIC or Sensor may be defective. Replace the PIC/Sensor.

E13, E15 Message: **Re-prep Sensor**
Operator Action: The sensor has an impedance that is too high. Check the cable connections and correct as necessary. If the message persists, check the impedance of the sensor. Re-prep or replace sensor as necessary.

E14 Message: **Sensor Not Connected**
Operator Action: Sensor or Patient Interface Cable is not connected. Patient Interface Cable or Sensor may be defective. Replace PIC or Sensor. If problem persists, DSC may require service. Replace DSC.

E15 (See E13) **Re-prep Sensor**

E16 Message: **Last Sensor Check Failed**
Operator Action: The operator aborted the last "Sensor Check" operation while the test was failing. Check connections, re-prep, or replace Sensor.

E17, E19 – E24 Message: **BIS Engine Comm. Error**
Operator Action: A communications error has been detected between the BIS Engine and the Host processor. If the error persists, the monitor requires service.

E18 Message: **BIS Engine Not Functional**
Operator Action: If the error persists, the monitor requires service.

E19 – E24 (see E17) **BIS Engine Comm. Error**

E25 Message: **Left side SQI Bad**
Operator Action: (2-channel monitoring only)

E26 Message: **Right side SQI Bad**
Operator Action: (2-channel monitoring only)

E27 Message: **SQI Below 50%**
Operator Action: The Signal Quality Index is poor. Note: the numeric display changes from a solid to an outlined number. Check Sensor/leads. May occur as a result of artifact such as those generated from motion or eyeblinks

E28 Message:	**SQI Too Low For BIS**
Operator Action:	The Signal Quality Index is unacceptable therefore the Trend variable cannot be calculated. Check Sensor. This may occur as a result of artifact such as those generated from motion or eyeblinks.
E29 Message:	**BIS < Low Alarm Limit**
Operator Action:	
E30 Message:	**BIS > High Alarm Limit**
Operator Action:	
E31 Message:	**Isoelectric EEG Detected**
Operator Action:	No discernible EEG activity is detected for several minutes; SR = 100. Check the patient. Check the leads for proper connection.
E32 Message:	**Review Data Lost**
Operator Action:	The contents of the data memory were lost and have been re-initialized. If the error persists, the monitor requires service.
E33 Message:	**Operating on Battery Backup**
Operator Action:	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 20 minutes.
E34 Message:	**Battery Power Low**
Operator Action:	There are only a few minutes of battery life left. Restore AC power to avoid automatic shutdown.
E35-E39, E43, E44, E48-E65, E69-E73, E75, E78-80, E87- E89, E110	
Message:	**Software Error**
Operator Action:	The monitor requires service.
E40 Message:	**Setup Memory Write Error**
Operator Action:	Can't save Setup data to non-volatile memory. Monitor requires service.
E41 Message:	**Real-Time Clock Write Error**
Operator Action:	Can't save time/date or data to non-volatile Real-Time Clock. Monitor requires service.
E42 Message:	**Can't Save Setup**
Operator Action:	This message should only appear when running on battery power, the battery is low, and the user attempts to save setup data. Restore AC power or save Setup data later.
E43, E44 (See E35)	**Software Error**

E45 Message: **No Updates From BIS Engine**
Operator Action: No processed data from BIS Engine in the last 10 seconds. If error persists, monitor may require service.

E46 Message: **BIS Engine Not Responding**
Operator Action: BIS Engine is not performing commands within the allowed time limits. If error persists, monitor may require service.

E47, E74, E81
Message: **Data Memory Write Error**
Operator Action: Problem writing data to non-volatile memory. Monitor requires service, but should continue to operate properly (data memory storage time will be reduced).

E48 – E65 (See E35) **Software Error**

E66 Message: **Printer out of Paper**
Operator Action: Check the printer. Make sure that it has paper. If the error persists, the printer requires service.

E67, E82, E85
Message: **Printer Error**
Operator Action: This indicates a printer hardware error. If the error persists, the printer requires service.

E68 (not used)

E69 – E73 (See E35) **Software Error**

E74 (See E47) **Data Memory Write Error**

E75 (See E35) **Software Error**

E76 Message: **Illegal Sensor for Demo**
Operator Action: A demo device is attached to the serial port, but the sensor connected through the DSC is not a valid demo sensor.

E77 Message: **Simulator Connected**
Operator Action: No action required. This message indicates that a demo device is attached to the serial port of the A-2000 and the A-2000 is not necessarily processing patient information

E78 – E80 (See E35) **Software Error**

E81 (See E47) **Data Memory Write Error**

E82 (See E67) **Printer Error**

E83 Message: **Printer Head is Up**
Operator Action: The print head on the printer has been lifted. Return it to the closed position. If the error persists, the printer requires service.

E84 Message: **Printer Disconnected**
Operator Action: The printer is no longer connected to the A-2000. Check the connection. If the error persists, the printer requires service.

E85 (See E67) **Printer Error**

E86 Message: **Printing Disabled**
Operator Action: The A-2000 is running on battery backup. When power is restored to the A-2000, printing will again be available.

E87- E89 (See E35) **Software Error**

E90 Message: **Printer Connected**
Operator Action: The printer has been successfully connected to the A-2000.

E91 Message: **Event Marking Disabled**
Operator Action: The ability to mark an event has been temporarily disabled. It will be re-enabled when event data extraction has been completed (less than 10 minutes).

E92 (not used)

E93 Message: **Sensor Ground Fault**
Operator Action: Disconnect and examine sensor; replace sensor if necessary. If problem continues, connect new DSC, restart monitor.

E94 Message: **Sensor Overcurrent**
Operator Action: Disconnect and examine sensor; replace sensor if necessary.

E95-E108 Message: **Invalid Sensor**
Operator Action: Replace sensor if necessary. The sensor is unusable for one of the following reasons:
E95 – The sensor has been connected too many times
E96-E102, E107 – The sensor contains invalid information
E103-E106, E108 – The sensor information could not be read.

E109 Message: **Sensor used > 24 hours**
Operator Action: The sensor has been in place for more than 24 hours. Disconnect and replace sensor.

E110 (See E35) **Software Error**

7.3 WHAT TO DO IF THE A-2000 REQUIRES SERVICE

Contact your local distributor to determine where servicing will occur. If it becomes necessary to return a unit directly to Aspect Medical Systems, follow the procedure below:

- Obtain return authorization. Contact Aspect's Technical Service Department to obtain a returned materials authorization (RMA) number. (The Technical Service phone number is printed on the back cover of this manual.) The RMA number should appear on the outside of the shipping container. Please provide the model number, serial number, and a brief description of the reason for return.

- Use the original shipping container, if available, or equivalent packaging to protect the product. Seal the package with plastic shipping tape rather than masking tape. Mark shipping or storage container FRAGILE.

- If the repair or replacement is covered by the warranty, Aspect will bear the costs of shipping the repaired or replacement product back to the user. All other shipping costs shall be paid by the user.

SECTION 8
8 SPECIFICATIONS, WARRANTY AND SOFTWARE LICENSE AGREEMENT

8.1 SPECIFICATIONS

This section lists specifications for the Aspect A-2000 BIS Monitor.

General Specifications:

- Product Description: BIS (Bispectral Index) monitor for display of processed data and real-time EEG waveforms
- Monitor Weight: 3.1 lbs (1.4 kg)
- Monitor Dimensions: 7.0 in wide x 6.8 in high x 4.0 in deep (17.5 cm x 16.9 cm x 10 cm)
- Digital Signal Converter:
  - Weight: 10.0 oz (0.284 kg) including integral cable
  - Dimensions: 2.6 in wide x 1.00 in high x 4.25 in deep (6.6 cm x 2.5 cm x 10.8 cm)
  - Cable Length: 12 ft (3.7 m) Integral DSC Cable
    4 ½ ft (1.4 m) from DSC to sensor connector
- Display Size: 3.4 in high x 4.5 in wide (8.5 cm x 11.25 cm)
- Digital Output: RS232 serial port, printer port
- Power Requirements: 100-240 VAC, 50-60 Hz, 1 ampere max.
- Electrical Safety: Conforms to: UL 2601, CSA 22.2 No. 601-1 and IEC 601-1
- Battery Backup: 20 minutes at full operation
  Recharge Time: 4 hours
- Software Updates: User-via RS-232 serial port
- Processors: Texas Instruments TMS 320C32 (50 MHz), Sharp LH77790 Risc (25 MHz)

EEG Specifications:

- Epoch Duration: 2 seconds
- Artifact Rejection: Automatic
- EEG Scales: 25 μV/div (+/- 1 mV Full Scale)
  Display Type – EEG: 5, 10, 25, 50 or 100 μV/div
- EEG Sweep Speeds: 25 mm/sec
  Display Type – EEG: 15, 25, or 30 mm/sec
- Computed Parameters: Bispectral Index, 95% Spectral Edge Frequency, Suppression Ratio, EMG, and Signal Quality Index
- User-defined Displays: TREND, DSA, the BIS Log, and real-time EEG waveforms
- Update Rate: 1 second for BIS Index, 10 seconds for Trend/DSA
- Event Markers: User selected
- Alarms: Auditory and visual, user adjustable limits
- Filters: ON (2 – 70 Hz with notch) or OFF (.25 – 100 Hz)
- Mode: Sensor automatically selects mode.

Digital Signal Converter Specifications:

- Analog to Digital Converter: Noise-shaped sigma-delta
- Sampling Rate: 16,384 samples/second
- Resolution: 16 Bits at 256 samples/second
- Input Impedance: 50 Mohms minimum
- Noise: < 0.3 μV RMS (2.0 μV peak-to-peak);
  0.25 Hz to 50 Hz
- Common Mode Rejection: (Isolation mode) 110 dB at 50/60 Hz to earth ground
- Bandwidth: **DSC – 2:** 0.16 – 800 Hz
  DSC – XP: 0.16 – 450 Hz

Type of Protection against Electric Shock of the System:

Class 1: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Degree of Protection against Electric Shock of the System:

Type BF: Equipment providing a degree of protection against electric shock regarding allowable leakage currents and reliability of the protective earth ground connection with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth.

Degree of Protection against effects of Cardiac Defibrillation:

The A-2000 system provides protection for the operator and patient during cardiac defibrillation.

Degree of Protection against the Ingress of Water:

Monitor degree of protection rating: IPX2 (ingress of water vertically dripping)
DSC degree of protection rating: IPX4 (splash proof)

Mode of Operation of the System:

Continuous: Operation under normal load for a normal period without exceeding the specified limits of temperature.

Classification:

MEDICAL ELECTRONIC EQUIPMENT

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.®
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH
UL 2601-1, IEC601-2-26
CAN/CSA C22.2 NO. 601.1, CAN/CSA 601.2.26
42SA

8.2 WARRANTY

Aspect warrants to the initial Purchaser that the A-2000 BIS monitor and the Digital Signal Converter ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Aspect's obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Aspect reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Aspect directly (see contact information on the back cover of this manual). Aspect will authorize Purchaser to return the Warranted Product (or part thereof) to Aspect. Aspect shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Aspect's property. In the course of warranty service, Aspect may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Aspect reasonably determines that a repair or replacement is covered by the warranty, Aspect shall bear the costs of shipping the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a Product to Aspect in unsuitable packaging, any physical damage present in the Product on receipt by Aspect (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

This warranty does not extend to any Warranted Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Aspect's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than Aspect; or that have been disassembled, serviced, or reassembled by anyone other than Aspect, unless authorized by Aspect. Aspect shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Aspect makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Aspect or an Aspect-authorized distributor or (c) with respect to any product sold under a brand name other than Aspect Medical Systems, Inc.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR ASPECT'S PRODUCTS, EXTENDS ONLY TO THE PURCHASER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ASPECT'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY ASPECT IN CONNECTION THEREWITH. ASPECT SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

8.3 SOFTWARE LICENSE AGREEMENT

The computer software ("Licensed Software") loaded on the A-2000 BIS Monitor ("System") is licensed, not sold, to you for use only under the terms of this license. Aspect Medical Systems, Inc. ("Aspect") reserves any rights not expressly granted to you. You own the System, but Aspect retains all ownership rights and title to the Licensed Software itself.

1. **LICENSE:** You are hereby granted the non-exclusive right to use the Licensed Software solely with the specific System on which the Licensed Software was provided to you.

2. **RESTRICTIONS:** You shall not transfer the Licensed Software in any manner from the System to any other computer or system without the prior written consent of Aspect. You shall not distribute copies of the Licensed Software or its related documentation to others. You shall not modify or translate the Licensed Software or its related documentation without the prior written consent of Aspect. The Licensed Software contains trade secrets and to protect them you may not decompile, reverse engineer, disassemble, or otherwise reduce the Licensed Software to a human-perceivable form. If you transfer the System, you have the right to transfer the Licensed Software provided that the transferee agrees to be bound by the terms and conditions of this License Agreement.

3. **TERMINATION:** This License remains effective until terminated. This License will terminate automatically without notice from Aspect if you fail to comply with any term or provision of this License. Upon termination of this License, you may not make any further use of the Licensed Software.

4. **LIMITED WARRANTY:** THE LICENSED SOFTWARE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY WITH RESPECT TO ITS MERCHANTABILITY OR ITS FITNESS FOR ANY PARTICULAR PURPOSE. ASPECT DOES NOT WARRANT THAT THE FUNCTIONS CONTAINED IN THE LICENSED SOFTWARE WILL MEET YOUR REQUIREMENTS OR THAT THE OPERATION OF THE LICENSED SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE OR THAT SUCH ERRORS IN THE LICENSED SOFTWARE WILL BE CORRECTED.

5. **LIMITATION OF REMEDIES AND DAMAGES:** ASPECT'S ENTIRE LIABILITY TO YOU FOR ACTUAL DAMAGES FOR ANY CAUSE WHATSOEVER, AND REGARDLESS OF THE FORM OF THE ACTION, AND YOUR EXCLUSIVE REMEDY SHALL BE LIMITED TO THE MONEY PAID FOR THE SYSTEM, WHICH INCLUDED THE LICENSED SOFTWARE.

IN NO EVENT SHALL ASPECT BE LIABLE TO YOU (I) FOR ANY INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, AND THE LIKE) ARISING OUT OF THE USE OF OR INABILITY TO USE ANY LICENSED SOFTWARE EVEN IF ASPECT OR ANY AUTHORIZED ASPECT REPRESENTATIVE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR (ii) FOR ANY CLAIM BY ANY OTHER PARTY.

6. **GENERAL:** This License Agreement will be construed under the laws of the Commonwealth of Massachusetts. If any provision of this License Agreement shall be held by a court of competent jurisdiction to be contrary to law, that provision will be enforced to the maximum extent permissible, and the remaining provisions of this Agreement will remain in full force and effect.

Should you have any questions concerning this License Agreement, you may contact Aspect by writing to Aspect Medical Systems, Technical Service. (See back cover for contact information.)

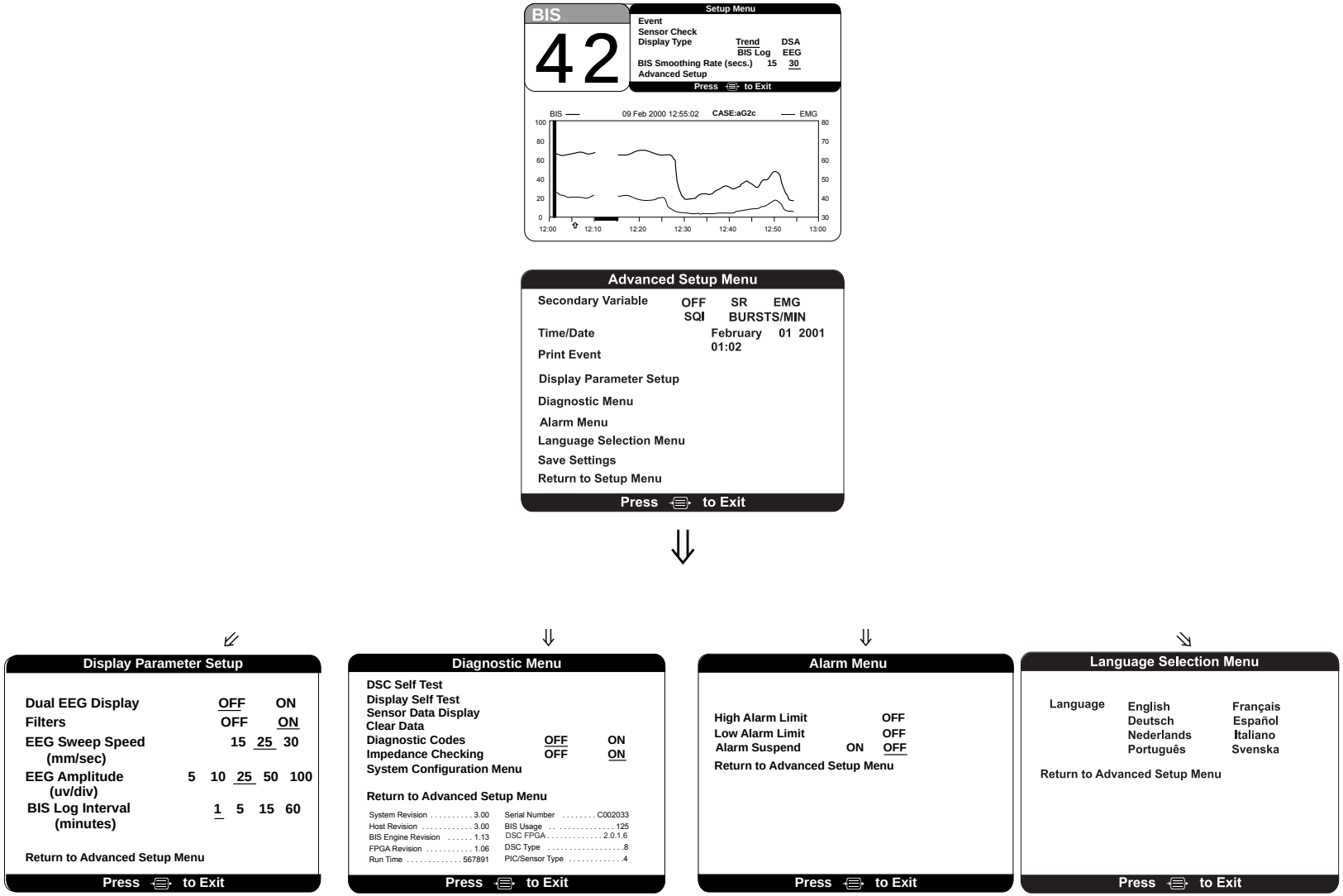
THIS LICENSE AGREEMENT IS THE COMPLETE AND EXCLUSIVE STATEMENT OF THE AGREEMENT BETWEEN YOU AND ASPECT AND SUPERSEDES ANY PROPOSAL OR PRIOR AGREEMENT, ORAL OR WRITTEN, AND ANY OTHER COMMUNICATIONS BETWEEN YOU AND ASPECT RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT.

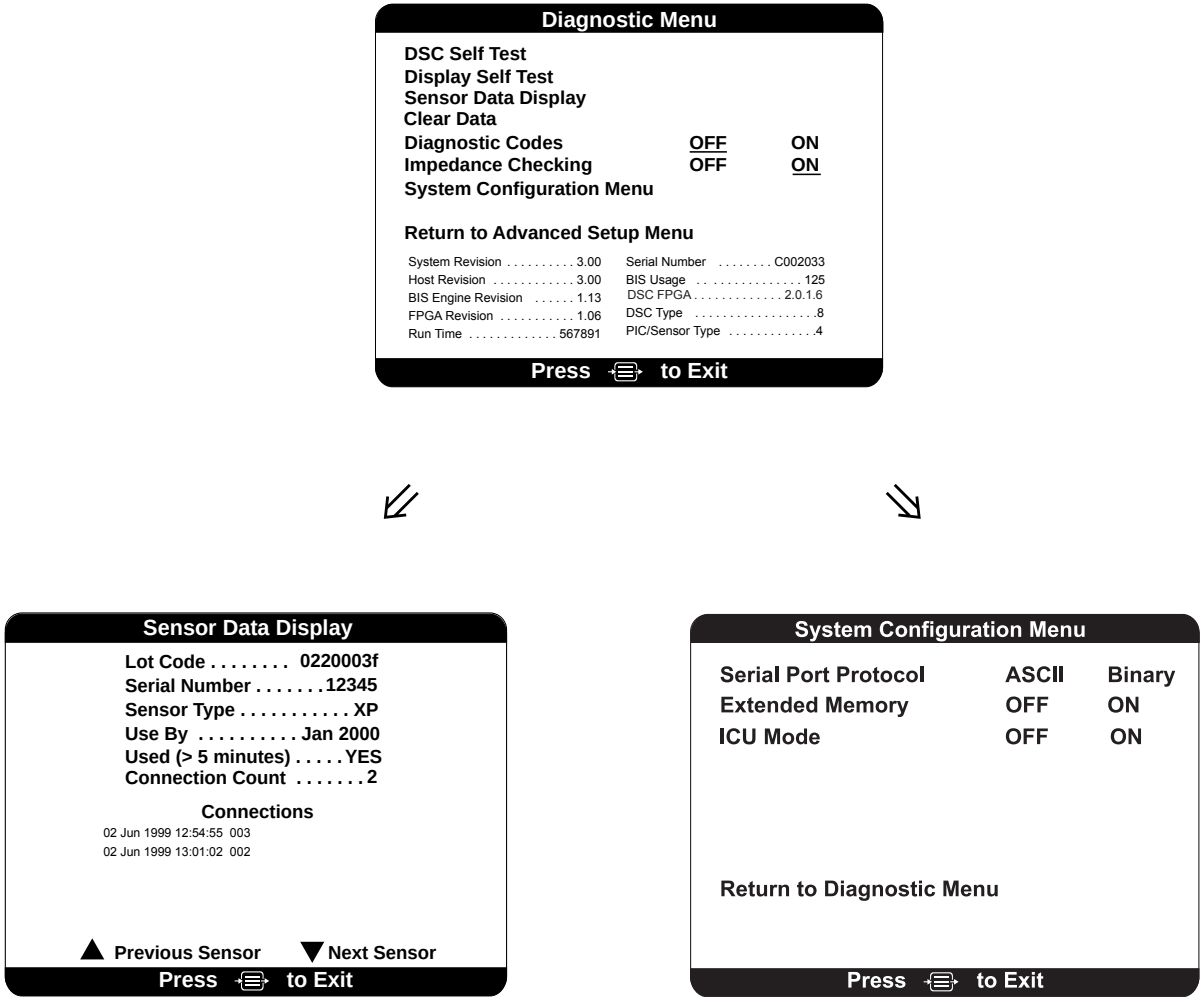
SECTION 9
9 APPENDIX

9.1 APPENDIX I – PROCESSED EEG VARIABLES

Variable Name	Description	Range
Bispectral Index (BIS)	The output from a multivariate discriminate analysis that quantifies the overall bispectral properties (frequency, power, and phase) throughout the entire frequency range.	0.0 – 100.0
Signal Quality Index (SQI)	A measure of the signal quality for the EEG channel source(s) that is calculated based on impedance data, artifact, and other variables. Not affected by Suppression Ratio.	0.0 – 100.0
EMG	The absolute power in the 70-110 Hz range. The power value is reported in dB with respect to 0.0001μV2. All the artifact detection is turned off for this variable.	30 – 80 dB Trend 30 – 55 dB Bar Graph
Suppression Ratio (SR)	The percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed.	0.0 – 100.0 %
Burst Count	The number of EEG bursts per minute, where a “burst” is defined as a short period of EEG activity preceded and followed by periods of inactivity (suppression).	0 – 20
Spectral Edge Frequency (SEF)	The frequency at which 95% of the total power lies below it and 5% lies above it.	0.5 - 30.00 Hz

9.2 A-2000 MENU MAP




Diagnostic Menu
DSC Self Test
Display Self Test
Sensor Data Display
Clear Data
Diagnostic Codes OFF ON
Impedance Checking OFF ON
System Configuration Menu
Return to Advanced Setup Menu
System Revision 3.00
Host Revision 3.00
BIS Engine Revision 1.13
FPGA Revision 1.06
Run Time 567891
Serial Number C002033
BIS Usage 125
DSC FPGA 2.0.1.6
DSC Type 8
PIC/Sensor Type 4
Press to Exit
Sensor Data Display
Lot Code 0220003f
Serial Number 12345
Sensor Type . . . . . XP
Use By . . . . . Jan 2000
Used (> 5 minutes) . . . . . YES
Connection Count 2
Connections
02 Jun 1999 12:54:55 003
02 Jun 1999 13:01:02 002
Previous Sensor
Next Sensor
Press to Exit
System Configuration Menu
Serial Port Protocol ASCII Binary
Extended Memory OFF ON
ICU Mode OFF ON
Return to Diagnostic Menu
Press to Exit

9.3 MENU LISTING

Default values are underlined

Setup Menu:

1. Event
2. Sensor Check
3. Display Type **Trend** DSA EEG BIS Log
4. BIS Smoothing Rate (secs.) **15** 30
5. **Advanced Setup:**
   - a. Secondary Variable **OFF** EMG Bursts/Min* SQI SR
   - b. Time/Date Month Day Year Hour Minute
   - c. Print Event
   - **d. Display Parameter Setup:**
     - Dual EEG Display** **OFF** ON
     - Filters OFF **ON**
     - EEG Sweep Speed (mm/sec) 15 **25** 30
     - EEG Amplitude (µv/div) 5 10 **25** 50 100
     - BIS Log Interval (minutes) 1 5 15 60
     - Return to Advanced Setup Menu
   - **e. Diagnostic Menu:**
     - DSC Self Test
     - Display Self Test
     - Sensor Data Display:
       - Sensor Data Screen
     - Clear Data
     - Diagnostic Codes **OFF** ON
     - Impedance Checking OFF **ON**
     - **System Configuration Menu:**
       - Serial Port Protocol **ASCII** BINARY
       - Extended Memory OFF **ON**
       - ICU Mode **OFF** ON
       - Return to Diagnostic Menu
     - Return to Advanced Setup Menu
     - Configuration Information
   - **f. Alarm Menu:**
     - High Alarm Limit **OFF**
     - Low Alarm Limit **OFF**
     - Alarm Suspend ON **OFF**
     - Return to Advanced Setup Menu
   - g. **Language Selection Menu:**
     - Language: English Français Deutsch Español Nederlands Italiano Português Svenska
     - Return to Advanced Setup menu
   - h. Save Settings
   - i. Return to Setup Menu

*This option will display only if a BIS Extend sensor is connected.
**This option will display only if BIS Quatro or BIS Extend sensors are connected.

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